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(71)(72) Applicant and Inventor: EDOGA, John, K. [US/US]; 3rd floor, 95 Madison Avenue, Morristown, NJ 07960 (US).

(74) Agents: TESCHNER, Michael, H. et al.; Lerner, David, Littenberg, Krumholz & Mentlik, 600 South Avenue West, Westfield, NJ 07090 (US).

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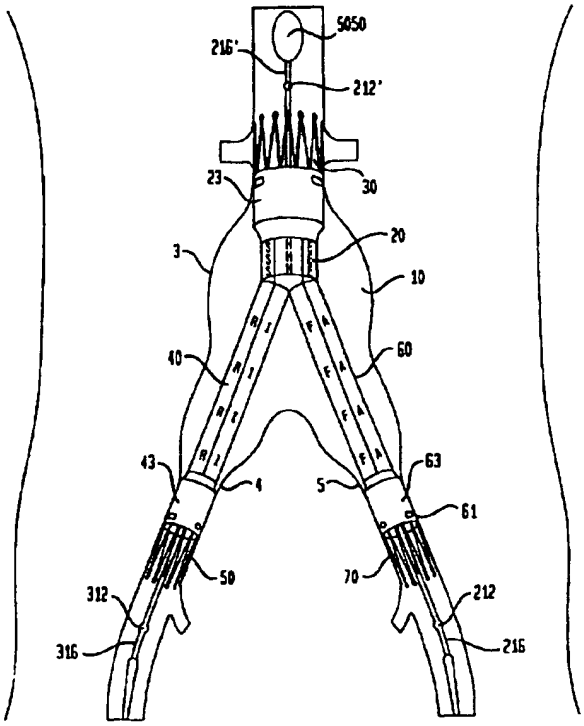
(54) Title: ENDOLUMINAL GRAFT REPLACEMENT OF ABDOMINAL AORTIC ANEURYSMS

(57) Abstract

The present invention relates to methods and devices useful in endovascular surgery for treating abdominal aortic aneurysms. Devices described include a mandril (210) and graft assembly (10) which is to be twisted and inserted into the vascular system of a patient. Both a new type of sheath and a laparoscopically placeable vascular band which may be used when doing endovascular surgery and the methods of their use are also described.



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DESCRIPTION

ENDOLUMINAL GRAFT REPLACEMENT OF ABDOMINAL AORTIC ANEURYSMS

TECHNICAL FIELD

The invention relates to methods of endovascular surgery and to devices useful in performing endovascular surgery. The present invention also relates to laparoscopic procedures for placing a band around a blood vessel which may be used in conjunction with endovascular surgery or endovascular grafting.

BACKGROUND ART

There are several medical conditions which currently require surgery and/or the use of an abdominal aortic graft. These conditions include: abdominal aortic aneurysms, aortic and iliac occlusive disease following balloon angioplasty and aorta-distal arterial embolization. Each of these conditions most commonly affects the aorta immediately below the take off or junction with the renal arteries through and including the area where the aorta divides into the common iliac arteries.

For illustrative purposes, consider a patient having an abdominal aortic aneurysm. An aneurysm is defined as a sac formed by localized dilatation of the aorta. Aneurysms can lead to occlusion and more notably rupture of the arterial wall and thus unconfined bleeding into the abdomen. If left untreated, the patient may die of internal bleeding.

One method of treating this disorder is through the use of an arterial replacement. However, even though the mortality rate for elective aneurysm resection is usually less than 5% for the average risk patients, the risk is much higher for patients with several combined conditions. In fact, the morbidity of the needed surgery is quite severe in this group of patients. The average hospital stay is ten to fourteen days, at a total cost of tens of thousands of dollars. For ruptured aneurysms, the hospital

mortality rate is approximately 75%, with greater than 2/3 of the deaths occurring during surgery or within a few hours after surgery. For survivors, the morbidity includes limb and bowel loss and renal failure requiring life long dialysis. When an aortic aneurysm ruptures, resource consumption related to care of the patient rises astronomically. There are also a great number of patients in whom co-morbid factors constitute relative or absolute contraindications to this type of surgery on an elective basis, such as patients with severe coronary artery disease or pulmonary insufficiency.

Another technique involves the insertion of a graft made of suitable material within the existing aorta and anchoring the graft in place such that it acts to carry blood through the afflicted portion of the aorta. This is analogous to fixing a leaking pipe by placing another pipe of smaller diameter within the existing pipe and in essence, bypassing the afflicted area of the aorta. However, the technique does have some problems which include difficulty in accurately sizing, delivering and correctly fixing the graft in a bifurcated blood vessel. For example, one problem is that until surgery begins, it is often difficult to know the exact length of a graft which will actually be required to reach from the affected area of the aorta just below the renal arteries down to and through the iliac arteries. Although surgeons are able to estimate the necessary length, a graft which is too long may buckle or kink once flow is restored. However, if the graft is too short when a stent is released to anchor the graft in place, it may expand in an already weakened portion of the aortic or iliac arteries and cause either rupture, leakage or other complications.

The biggest potential problem is getting both of the lower or iliac ends of the graft, which are to be disposed in the right and left iliac arteries, properly aligned and positioned while at the same time, controlling the placement of the upper or aortic end of the graft. While a

number of techniques have been suggested, the most common one uses two guide wires which are inserted through the common femoral artery of one leg and then up into the body. A first guide wire is inserted through the common femoral artery in one leg such that its free end dangles in the aorta around the junction with the renal arteries. The other guide wire is fed in through the same leg and crosses over from one iliac artery into another and out through an incision in the common femoral artery of the other leg. For example, see Figures 9 through 12 and the accompanying text of *Baron et al.*, U.S. Patent No. 5,360,443. The loose guide wire is used to guide the entire stent and graft assembly into the abdominal aorta above the iliac divide. The aortic or proximal end of the graft is exclusively fed through the femoral artery with the two iliac ends of the graft trailing behind. Thereafter, the second guide wire, which is looped up through both iliac ends of the graft, is used to help try to position the crossover iliac end into proper position in the iliac artery of the other leg. Other than the obvious difficulties in maneuvering the device, it is difficult to ensure that the graft does not become twisted and blocked during deployment. It is also difficult to control the placement of the iliac portion of the graft which is being maneuvered into the non-insertion iliac artery.

Baron et al. also discloses insertion of an apparatus intralumenally to the aorta and in particular, to a ruptured aneurysm, through the axillary artery in the patients arm. For example, see Figures 13 and 14. However the use of this method and device appears to be limited in connection with ruptured aneurysms and *Baron et al.* does not disclose the ability to accommodate a bifurcated graft.

Palmaz et al., U.S. Patent No. 5,316,022, discloses inserting two individual bifurcated grafts, rather than one, through the individual femoral and iliac arteries and up into the aorta. This leads to uniform sacrifice of the internal iliac circulation and would only be feasible in

patients who already have both internal iliac arteries occluded. Also, the proximal end of the double individual graft-stents will not likely be able to produce a complete seal.

There are other problems with endovascular grafting techniques which often limit the number of patients who qualify for this type of surgery. For example, when treating an abdominal aortic aneurysm with endovascular surgery, it may be difficult to actually deploy a stent within the abdominal aorta beneath the junction with the renal arteries. The aneurysm may be disposed such that there is a very little portion of healthy abdominal aorta in which to anchor such a stent. In addition, deployment of a stent under such circumstances may actually rupture the abdominal aneurysm.

An additional problem is common in younger patients who have successfully survived endovascular surgery. As these patients age, the blood vessels may expand and leakage may occur. In extreme cases, the vessel could expand beyond the ability of the stent to maintain contact therewith and the stent and graft could actually move. In that instance, the graft could fold and become an obstruction. Successfully addressing this problem would allow endovascular surgery to be more useful to a wider range of patients and could help prevent potentially disastrous complications long after surgery.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, there is provided a graft useful in endovascular surgery. The graft includes at least a first hollow member having a first end, a second end and an extended portion therebetween. Preferably, disposed in proximity to the first end, i.e., at or adjacent to the first end, there is provided indicia which can indicate the location of the first end of the first hollow member,

even when it is disposed within the blood vessel of a patient during surgery.

Most preferably, second and third hollow members are also provided, each of which are of a structure as described above. The three hollow members are all joined, i.e., connected or integrally formed at their respective second ends and therefore, the hollow members are all in fluid communication with each other. In a particularly preferred embodiment, the graft can also include indicia or other devices which can indicate the position and/or the axial orientation of each limb of the graft, i.e., whether or not that limb is twisted and/or correctly positioned. The indicia disposed at the first end of each hollow member can serve both of these functions.

In another aspect of the present invention, there is provided a graft-stent assembly. This assembly includes a graft comprised of first, second and possibly third hollow members, which are joined and in fluid communication with each other, as previously described. Each of the hollow members include an opening at a first end thereof and each have a stent disposed and attached within those openings. It is preferred that at least one of the hollow members includes indicia associated with its first end which can indicate the position of the first end of that hollow member, even when it is disposed within a blood vessel. In addition, or in the alternative, the bifurcated graft-stent assembly may include indicia disposed along its length which can indicate the axial orientation of the hollow members, i.e., whether or not the hollow members are twisted when disposed within a blood vessel.

These bifurcated graft-stent assemblies can be combined with a plurality of single and or dual lumen mandrils which releasably retain each of the hollow members and their associated stents. The resulting device, created by the association of the graft-stent assembly and a

plurality of mandrils, can be used in a method of introducing a bifurcated graft into a bifurcated blood vessel.

For present purposes, a bifurcated blood vessel can be conceptualized as including at least a first portion, a second portion and a third portion, said first, second and third portions all being joined and in fluid communication. These "portions" are themselves hollow tubes, i.e., veins and arteries, through which blood flows. To use the devices of the present invention, the first end of the third hollow member of the graft-stent assembly and the third stent attached thereto are releasably retained or attached to a first mandril while the first mandril bridges the second and the third portions of the vessel. The first end of the third hollow member and the third stent are then fed into the second portion of the vessel.

Next, the first end of the first hollow member and the first stent associated therewith are releasably retained or attached to a second mandril while the second mandril bridges the first and the second portions of the vessel. At least the first end of the first hollow member and the first stent are then fed into the second portion of vessel.

Finally, the first end of the second hollow member and the associated second stent is bound, retained or attached to a third mandril. The second hollow member and the second stent are then fed into the second portion of the vessel. This hollow member can also be releasably attached to a mandril.

The bifurcated graft-stent assembly is then manipulated such that the first hollow member and at least a part of the second mandril are disposed within the first portion of the vessel. At the same time, the third hollow member and at least a part of the first mandril are disposed within the third portion of the vessel. The second hollow member and at least a part of the third mandril are disposed within the second portion of the vessel. The first ends of the hollow members are then released and the

stents expanded to anchor the hollow bifurcated graft-stent assembly within the vessel. Finally, the mandrils are withdrawn.

Preferably, the first mandril is withdrawn from the first portion of the vessel, the second mandril is withdrawn from the second portion of the vessel and the third mandril is withdrawn from the third portion of the vessel through access points closely associated with those portions of the vessel.

In a particularly preferred embodiment of the present invention, at least one, and preferably two of the hollow members are twisted prior to feeding the hollow members into the blood vessel. Even more preferably, the step of twisting the hollow members takes place prior to releasably attaching them to the mandrils.

Of course, these limbs cannot remain twisted. Therefore, the present invention also provides the step of untwisting the intentionally twisted hollow members prior to releasing same from the mandrils. By the use of certain indicia which can be observed when the graft-stent assembly is disposed within the blood vessel, it is possible to verify the actual axial orientation of the hollow members to confirm that they have been fully untwisted prior to deploying the stents.

The present invention is ideally suited for endovascular surgery such as the bypassing of an abdominal aortic aneurysm. The methods and devices described herein allow the surgeon an unparalleled level of control of each end of the graft. This allows the surgeon to position the graft-stent assembly exactly where he or she desires. In addition, because of the unique construction of the graft and preferably a graft-stent assembly, the surgeon will have a hitherto unknown level of confidence in the actual location of the ends of the graft. For example, radiopaque labels can be associated with the ends of the graft. This means that they may be at the graft's edge or adjacent the end. This indicia can

also be spaced away from the edge of each end of the graft by a predetermined amount. These radiopaque indicia precisely indicate the position of the graft during surgery.

In a particularly preferred embodiment in accordance with the present invention, the graft-stent assemblies described herein are provided to the surgeon factory pre-assembled. This means that they can be subject to rigorous quality control testing which reduces the failure rate. In addition, the provision of pre-assembled graft-stent assemblies will reduce the amount of surgical time required prior to a surgical procedure. Finally, because the graft-stent assembly is pre-made, it is possible to associate a radiopaque or other functionally equivalent indicator at the extreme ends of the graft. This allows the surgeon to know the exact position of the graft when it is in the blood vessel. It would be difficult to do this using traditional grafts as they often need to be shortened and therefore, the indicia would be cut off. Of course, the methods in accordance with the present invention could be used equally well with a traditional graft-stent assembly assembled by the surgeon on site.

The graft can also be provided with other sorts of indicia which will allow the surgeon to ensure that the individual limbs of the graft are properly oriented and are not twisted or axially rotated prior to deployment. This overcomes a significant problem experienced during traditional methods of endovascular surgery using bifurcated grafts. The use of this indicia has another unexpected advantage as well. Because the graft is provided with indicia which allows the surgeon to determine the axial position or orientation of same, it is possible for the surgeon to intentionally impart twisting to the graft during surgery, knowing full well that that orientation can be reversed when desired.

Of course, without the present invention, it would be difficult to imagine why one would wish to impart twisting or axial rotation to a

graft. In fact, twisting of the graft during endovascular surgery is one of the most persistent problems and complicating factors in this type of surgery. However, when twisting is utilized in accordance with the methods described herein, a number of advantages are realized. First, by twisting one or more of the limbs of the graft/graft-stent assembly, it is possible to impart additional rigidity to the structure, despite the fact that the individual mandrils used are only connected via the graft-stent assembly. This allows a greater degree of control when manipulating the graft-stent assembly into place. Additionally, twisting the graft-stent assembly reduces its cross-sectional area, making its introduction into a vessel and its movement therethrough less stressful on the vessel. It also keeps the full length of each limb in a neat and generally orderly manner and provides additional control advantages.

In accordance with another aspect of the present invention, a device is provided which is used for wrapping around a length of a blood vessel. The device can be used in conjunction with the methods and devices for endovascular surgery as described above, or with any other endovascular method as well. This device generally includes a sheath having a first end, a second end and a body disposed therebetween. A connector is provided to form a closed band. For example, the second end can also be attached to and/or adjacent to the first end of the sheet. Alternatively, two portions of the band, each spaced from the first and second ends thereof, can be attached.

The sheath is preferably sized and shaped to allow it to be introduced into operative proximity of a blood vessel laparoscopically, i.e., through a trocar. The sheath is also preferably composed of a material which is medically inert and sufficiently flexible enough to allow manipulation and resilient enough to resist the expansion of the vessel. More preferably, the sheath has a structure which will permit tissue

ingrowth and minimize devascularization (loss of blood flow to the wall of the vessel).

A method of laparoscopically placing a band around a blood vessel is also provided. This method includes providing access to a blood vessel through a trocar. A flexible band is then introduced into the proximity of the blood vessel through the trocar. The band is wrapped around the blood vessel and secured. In a preferred embodiment, a stent is anchored into a blood vessel prior to securing the band around that portion of the vascular system. In an alternative, yet no less preferred aspect of the present invention, a stent is expanded within that portion of a blood vessel which is wrapped by the band.

Finally, in accordance with another aspect of the present invention, there is a device provided for restraining a stent in a compacted configuration for deployment. The device includes a first sheath having a first diameter and a second sheath having a second diameter which is larger then the diameter of the first sheath. At least a portion of the first sheath is disposed within the second sheath, the first sheath being movable within the second sheath. Moreover, the first sheath is sized and shaped so as to engage and restrain a stent retained therein in a compacted position. In a particularly preferred embodiment, the first sheath is slidably attached to the second sheath such that it can move longitudinally for a specified distance, but has very limited, and preferably substantially no ability to rotate axially.

BRIEF DESCRIPTION OF THE DRAWINGS

References made herein to the following Figures:

Figure 1 - A perspective view of a graft-stent assembly in accordance with the present invention.

Figure 2 - A perspective view of a second form of graft-stent assembly in accordance with the present invention.

Figure 3 - A schematic front elevational view of a self-expandable stent.

Figure 4 - A diagrammatic view of a torso of a patient and a portion of the vascular system, including the aorta, the abdominal aorta, the iliac and femoral showing the course of guide wires threaded through a graft.

Figure 5 - A perspective view of a single lumen mandril and sheath.

Figure 6 - A partial diagrammatic view of a torso of a patient showing a single lumen mandril threaded over a guide wire emanating from the left groin through the left femoral artery, the left iliac artery into the right iliac artery, the right femoral artery and then out through the right groin.

Figure 7 - A diagrammatic view of a torso of a patient showing the single lumen mandril threaded over a guide wire traversing the groin of a patient.

Figure 8 - A partial diagrammatic view of a torso of a patient showing the threading of a graft-stent assembly over a first guide wire.

Figure 9 - A diagrammatic exploded view of the first end of a graft-stent assembly as it approaches a single lumen mandril 4 releasable engagement therewith.

Figure 10 - A partial diagrammatic view of a torso of a patient showing a graft-stent assembly showing the twisting of a limb around a guide wire.

Figure 11 - A partial diagrammatic view of a torso of a patient showing the compression of the stent of a graft-stent assembly into the housing of a single lumen mandril.

Figure 12 - A diagrammatic perspective view of the first end of a graft-stent assembly compressed into the housing of a single lumen mandril.

Figure 13 - A partial diagrammatic view of a torso of a patient showing the twisted limb of a graft-stent assembly retained within the housing of a mandril by a sheath.

Figure 14 - A diagrammatic perspective view of a graft-stent assembly retained in connection with a mandril by the use of a sheath.

Figure 15 - A partial diagrammatic view of a torso of a patient showing the threading of a second single lumen mandril through the right femoral, right iliac and abdominal aortic arteries over a guide wire, as well as the threading of the guide wire through the graft-stent assembly.

Figure 16 - A partial diagrammatic view of a torso of a patient showing a graft-stent assembly with two limbs twisted and releasably retained on individual single lumen mandrils.

Figure 17 - A diagrammatic perspective view of a double lumen mandril, in accordance with the present invention, as well as an associated sheath.

Figure 18 - A diagrammatic perspective view of the threading of a double lumen mandril over a plurality of guide wires as it is brought into engagement with a graft-stent assembly.

Figure 19 - A partial diagrammatic view of a torso of a patient showing the position of a bifurcated graft-stent assembly and the associated mandrils prior to deployment wherein each of the individual limbs of the bifurcated graft are disposed in an individual blood vessel.

Figure 20 - A partial diagrammatic view of a torso of a patient showing the deployment of a bifurcated graft and removal of the individual mandrils.

Figure 21 - A partially cut-away perspective view of an occluding catheter which can be used to interrupt the flow of blood while allowing one to work through its center.

Figure 22 - A partial cross-sectional view of the upper chamber of the device of Figure 21.

Figure 23 - A front elevational view of an obturator used for delivering the catheter in Figure 21.

Figure 24 - A plain view of a tool useful for compressing a self-expanding stent into the housing of a single or dual lumen mandril.

Figure 25 - A perspective view, in partial cross-section, showing a single lumen mandril on a guide wire covered by an inner and outer sheath in accordance with the present invention and a locking and retracting mechanism useful for moving the sheaths relative to one another and to the mandril.

Figure 26 - A partial perspective view of the sheath assembly illustrated in Figure 25 wherein the inner sheath is advanced such that its fingers at least partially cover the housing of the mandril.

Figure 27 - A perspective view, in partial cross-section, of the locking device, sheath and housing illustrated in Figure 25 wherein both inner and out sheath have been advanced over the housing of the mandril.

Figure 28 - A perspective view, in partial cross-section, of a single layer sheath covering the housing of a mandril, with a locking and retracting device illustrated in the extended position.

Figure 29 - A perspective view in partial cross-section, of the device illustrated in Figure 28 with the sheath and locking device in the retracted position.

Figure 30 - A perspective view of an alternate embodiment of a sheath in accordance with the present invention where the inner sheath is

shorter than the outer sheath and is slidably associated therewith, although its range of movement is limited.

Figure 31 - A perspective view of the sheath of Figure 30 in relation to the first end of a graft-stent assembly.

Figure 32 - A perspective view of the sheath illustrated in Figure 30 as the outer sheath is advanced over the inner sheath.

Figure 33 - A perspective view of the sheath from Figure 30, wherein both the inner and outer sheath have advanced over the housing of the mandril to releasably retain a stent and the first end of a graft-stent assembly.

Figure 34 - A perspective view of the inner sheath in accordance with the sheath shown in Figure 30.

Figure 35 - A diagrammatic view of the abdominal aortic region showing a deployed graft-stent assembly in accordance with the present invention in place.

Figure 36 - A diagrammatic view of the abdominal aortic region showing a laparoscopically introduced band first surrounding a portion of the abdominal aorta.

Figure 37 - A diagrammatic view of the abdominal aortic region showing the suturing of one end of the band around the abdominal aorta so as to create a closed band.

Figure 38 - A diagrammatic view of the abdominal aortic region showing the sutured band illustrated in Figure 37.

Figure 39 - A diagrammatic view of the abdominal aortic region showing the band illustrated in Figures 36-38, with the extended portion above the sutures removed.

Figure 40 - A diagrammatic view of a laproscopically introducable band having apertures disposed therein to allow ingrowth and retard devascularization.

BEST MODE OF CARRYING OUT INVENTION

In accordance with the present invention, the graft can be either bifurcated or non-bifurcated. It should be sized and shaped for introduction into either a straight or branched vessel without gaps, leaks or gathers. Any graft which is physiologically acceptable, is able to be manipulated as discussed herein and which meets the other requirements known to those of ordinary skill in the art for vascular grafts, would be acceptable. However, woven or knitted Dacron or PTFE grafts such as those in conventional use are preferred.

Preferably, the graft is provided or produced as part of a graft-stent assembly. The graft-stent assembly includes a graft having at least one expandable stent disposed within at least one aperture of the graft. Most preferably, a stent would be disposed within each aperture of the graft.

An example of a bifurcated graft-stent assembly in accordance with the present invention is illustrated in Figure 1. The assembly 10 illustrated therein includes a graft 10' constructed of PTFE or similar polymeric film material. Suitable grafts 10' are currently available from C.R. Bard, Inc. of 129 Concord Road, Billercia, MA 01821-4699, sold under tradename VELEX or Meadox, a subsidiary of Boston Scientific Corp., of 1 Boston Scientific Place, Natick, MA, sold under the tradename HEMASHIELD. A PTFE graft 10' shown in Figure 1, includes three substantially hollow members joined together in fluid communication with one another. By joined, it is understood that graft 10' can be formed in a plurality of tubes which have been joined such that their lumens are connected; however, the term also encompasses grafts that are integrally formed in a single piece. The first hollow member 20 includes a first end 21 and a second end 22. The second hollow member 40 also has a first end 41 and a second end 42. The third hollow member 60 has a

first end 61 and a second end 62. The second end 22 of the first hollow member 20 is joined to or integrally formed with the second end 42 of the second hollow member 40, as well as second end 62 of third hollow member 60. Thus, the three hollow members 20, 40 and 60 respectively, are joined and arranged in fluid communication with each other, meaning that the hollow members are joined such that fluid passing through one is able to flow into and through the others, as well. The first ends 21, 41 and 61 of each of the hollow members also define apertures. Each hollow member can further be divided into a flexible, radially expandable region 23, 43, and 63, respectively and a generally non-radially expandable, but axially expandable region 24, 44, and 64, respectively. In a PTFE graft, the radial expansion regions can be produced by using a stretched or expandable PTFE while the axially expandable regions can be made of a less flexible form of PTFE.

Figure 2 illustrates another graft-stent assembly 10a, using a Dacron graft 11. With a Dacron graft 11, as illustrated in Figure 2, the expandability of the radially expandable regions adjacent to the first ends 21a, 41a, and 61a of the first hollow member 20a, second hollow member 40a and third hollow member 60a respectively, are created by vertical crimping which allows these portions of the graft to passively expand to a diameter greater than that achievable by the generally axially expandable portions of the graft 24a, 44a, and 64a, respectively. However, with the use of a Dacron graft 11 as illustrated in Figure 2, the accordion-pleating of the axially expandable portion 24a, 44a, 64a of the graft allows for extension longitudinally but does not permit for the radial expansion exhibited by the vertically crimped areas adjacent the extremities of the graft. The use of such expandable portions 23a, 43a, and 63a respectively, not only allows one to accommodate stents as described herein, but also allows for the expansion of the graft to accommodate the widening of the

blood vessel as the patient ages, thereby allowing the maintenance of a fluid-tight seal once the graft is implanted within a blood vessel.

In a particularly preferred embodiment of the present invention as shown in Figure 1, disposed in association with each first end 21, 41, and 61, respectively of the graft 10', there is provided a radiopaque label, thread, imprint or other structure which will be visible to the surgeon during endovascular surgery. These can be nothing more than simple radiopaque lines 25, 45, and 65 provided at or adjacent to the first ends of each of the hollow members of graft 10' of graft-stent assembly 10. (These lines are illustrated as 25a, 45a and 65a in Figure 2) This allows the surgeon to precisely identify the location of the ends of the graft while it is being manipulated into position during surgery. The surgeon may also insure that the graft is fully deployed because the distance between the label 25 at the first end 21 of the first hollow member 20 and radiopaque label 45 at the first end 41 of the second hollow member 40 should be the same as the distance between radiopaque line 25 and radiopaque line 65 at the first end 61 of the third hollow member 60 if a full deployment is required (also assuming a symmetrical graft).

While radiopaque labeling of grafts in general is not new, the use of radiopaque labels in this manner is a significant departure from the prior art. Currently, grafts which are sold commercially include limbs, which are significantly longer than would be useful in all but rare circumstances. This is done to allow the surgeon to specifically cut a graft down to the appropriate length. Thereafter, the surgeon will prepare the graft by sewing stents to the various openings thereof.

In accordance with one preferred aspect of the present invention, however, a surgeon will order a graft-stent assembly not just by the width or diameter of the various hollow members, but also by their length. The assembly 10 will be provided pre-assembled with stents and

ready for use. This means that it will not be necessary to cut the graft thereby cutting off a radiopaque label placed at the extremity. The use of factory prepared stent-graft assemblies 10 provides other advantages as well because it allows for the effective use of quality controls to assure product safety and reduce failure rate.

It is also possible to provide a plurality of lines, rings, or other graduation marks up and down the entire length of the graft, or at least for some distance spaced inwardly from the first ends 21, 41, and 61 respectively, to allow for one hollow member or the other to be cut if needed to correspond to the vasculature of a particular patient without completely loosing the ability to judge the position of the extreme end of that hollow member.

Graft-stent assembly 10 also preferably contains, arranged adjacent to the first ends 21, 41, and 61 respectively, of first, second and third hollow members 20, 40 and 60 respectively, additional radiopaque marks which allow the surgeon to judge the rotational position or the extent of "twisting" of the individual hollow members. This is also referred to herein as determining the axial orientation of a portion of the graft or the graft stent assembly. One problem often encountered in doing endovascular surgical procedures in accordance with the traditional methods is the twisting of one limb or another. Conventionally, significant efforts are made to avoid such twisting. By the practice of the present invention, this problem can be dramatically reduced, if not eliminated. Indeed, in accordance with a preferred aspect of the present invention, twisting may actually be intentionally imparted to the graft.

Each of the first ends 21, 41, and 61 are provided with a first radiopaque label 26, 46, and 66 each of which is a square in Figure 1. Each of these is located on the same side of each hollow member when the graft is in its extended position and proper orientation. Similarly, labels

27, 47, and 67 are provided having an identical shape to each other (a circle in Figure 1) and relative location on the other side of each limb of the graft assembly 10. If in a fluoroscope, each of these labels shows up in the positions indicated in Figure 1, then it is less likely that any limb of the graft is twisted. Of course, it is possible to combine the function of radiopaque labels 25, 26, and 27 such that the markings indicating twisting also indicate the proximity of the first ends 21, 41, and 61 of graft 10. These labels are illustrated in Figure 2 as 26a, 66a, 27a, 47a and 67a, respectively.

In an even more preferred aspect of the present invention, additional radiopaque labels are provided to ensure that the entire length of graft-stent assembly 10 is not twisted just prior to deployment. These additional radiopaque labels 28 and 29 should be positioned along each of the hollow members. As illustrated in Figure 1 label 28 is a letter or a series of letters, in this case "S", "H", "E", "R", "I", "F" and "A". It is important that the letters, group of letters or other symbols used be selected to ensure that upon quick visual inspection under a fluoroscope, laparoscope or other functionally equivalent device, it can be readily determined that each segment of each hollow member is untwisted. Therefore, a plurality of such labels may be necessary running the length of each hollow member. It is important that the radiopaque labels quickly apprise the surgeon of the actual orientation of the graft 10. For example, if a series of three dots were used instead of the letters illustrated for radiopaque labels 28, then if a segment of the graft-stent assembly 10 were twisted 180°, three dots in a row could still be apparent to the surgeon. The surgeon would not necessarily know that those three dots are disposed on the backside of graft 10 rather than on the front side thereof. However, the use of the letters "S" "H" and "E", for example, as illustrated in Figure 1, would be unmistakable when backwards, thereby instantly

apprising the surgeon of the improper orientation of that portion of graft-stent assembly 10. The use of a line 29, particularly in combination with other radiopaque labels, can also apprise the surgeon of the twisting of the hollow members, as well as providing the surgeon with a good center line indication of the positioning of the graft-stent assembly 10. Such a system is particularly important when used in combination with the methods of the present invention, as many of those methods require the intentional twisting of one or more of the hollow members. That creates a unique situation in that it intentionally imparts exactly that which those of ordinary skill in the art have always attempted to avoid.

Of course, the use of a radiopaque labeling system as described herein would be useful in any form of endovascular surgery. Therefore, grafts which are not a part of a graft-stent assembly, but which use such devices as radiopaque labels 25, 26, 27, 28 and 29, are specifically contemplated as part of this invention.

Finally and according to one aspect of the present invention, stents are provided and affixed within the apertures at the first ends 21, 41, and 61 of hollow members 20, 40, and 60 respectively. These stents 30, 50, and 70 respectively, can be either balloon expandable or self-expanding stents. Any stent currently useful for these purposes may be used. However, in a preferred embodiment, the stents used are of a double stranded, interwoven self expandable type as illustrated in Figure 3.

The stent 100 is generally cylindrical, and is comprised of two interwoven metal or alloy wires 101 and 103. The wires can be made of any material such as titanium, stainless steel, or known memory materials, which return to their original shape after reasonable deformation. Wire 101 is a closed loop which zigzags back and forth to define a generally hollow cylindrical boundary, wherein portions of the wire extend from one planar edge of the cylindrical boundary to the other

planar edge of the cylindrical boundary, and wherein such portions of the wire are generally at an angle to the planes defined by such planar edges. In other words, wire 101 forms a set of consecutive triangles extending around the surface of a cylinder, with the apex 109 of alternating triangles reaching the top plane 105 of the cylinder and the opposing side of the triangles being open and at the bottom plane 107 of the cylinder.

Stent 100 also includes a second wire 103 which has a nearly identical structure to wire 101. However, for every apex 109 of the first wire 101 at the top 105 of the cylinder, there is an apex 111 of the second wire 103 directly opposite apex 109 at the bottom 107 of the cylinder. The two wires 101 and 103 intersect one another midway between the top 105 and bottom 107 planes at a plurality of points 113. Wire 101 remains straight and wire 103 loops around wire 101 in alternating directions forming a loop at midpoint 113. At midpoint 113, wire 101 may have a short portion which is parallel to the top and bottom planes 105, 107 level in order to facilitate the connection. The size of the loop should be sufficient to pass not only wire 101, but also to pass a suture thread. Thus, a surgeon can suture a graft to stent 100 by attaching the graft to the stent at midpoints 113.

It is preferable that the apices 109 and 111 do not lie in the same cylindrical surface generally defined by the stent. Rather, the apices extend farther outward and away from the center of the cylinder than the rest of the stent. The extended apices in the configuration shown allow for the elimination or minimization of metal fatigue or stress, particularly when compared to stents which may be formed with hard corners. This structure also helps to maintain dynamic tension over a longer periods of time. Rather than crimping the stent at the apices, it is preferable that the apices be somewhat bulbed shaped to aid the performance of the stent as it expands from its contracted position. Other stents, such as a Gianturco Z

stent produced by Cook Co., of New Jersey, may also be used. The stents are attached within the apertures at the ends of the graft such that at least a portion of the stents are exposed.

As previously noted, factory manufacturing of these graft-stent assemblies allows for rigorous pre-implantation testing to ensure durability of the stent-graft joints, as well as the possibility of defining acceptable performance limits for the assembly. This also provides for a more cost effective way of delivering this device as it requires less surgical time to prepare the stent-graft assembly by the surgeon immediately prior to an operation.

For illustrative purposes only, a graft-stent assembly 10 or 11 can be explained in terms of the dimensions of the diameters of the non-radially expandable portions 24, 44, and 64 of the first, second and third hollow members 20, 40, and 60 respectively. Thus, for example, an 18 mm x 9 mm bifurcated aortic graft would have a first hollow member 20 whose diameter was 18 mm and whose second and third hollow members, 40 and 60 respectively, would each have a diameter of 9 mm. The expandable portion 23 of the first hollow member 20 would be expandable radially to as much as 27 mm or more, while the expandable ends 43 and 63 of the second and third hollow members 40 and 60 would be expandable to as much as about 13.5 mm or more. Other fixed diameters such as 16 mm x 8 mm, 14 mm x 7 mm or even 12 mm x 6 mm would be useful for an average male patient and female patients, while a diameter of up to about 20 mm by about 10 mm may be necessary for larger patients. It is preferable that the grafts would be available in half-centimeter increments in terms of length between about 14 cm for shorter patients to about 19 cm for larger patients. Pleated Dacron grafts such as those illustrated in Figure 2 may be expanded to an even longer length. The

stents are generally 3 cm in length with 1 to 1.5 cm of the stent being covered by the graft, leaving the remainder uncovered.

It is also recommended that a portion of the expandable regions, for example, radially expandable region 23 of hollow member 20, remain free of attachment to a stent 30 to permit the stent and the stented portion of the graft to be collapsed into the housing of a mandril as discussed herein. This transitional region is disposed between radially expandable region 23 and non-radially expendable region 24.

It may be helpful when considering the surgical procedures described herein to refer to Figure 4, which includes representation of a patient and a portion of the patient's circulatory system. In Figure 4, the abdominal aorta 3 is shown as including an aneurysm 7 and an aortic neck 6 disposed beneath the junction of the abdominal aorta and the renal arteries. The right iliac artery 4 and right femoral artery 4', as well as the patient's left iliac artery 5 and left femoral artery 5' are illustrated. Three incisions 8A, 8B and 8C are made in the patient adjacent to shoulder, right groin and left groin respectively. Incision 8A exposes and provides access to, in this case, the left axillary artery and incisions 8B and C expose and provide access to the right and left common femoral arteries, respectively. The superficial femoral, as well as the profunda femoral arteries may also be exposed and controlled with vessel loops or umbilical tape.

A first guide wire 1 which bridges the right iliac artery 4 and the left iliac artery 5, and a second guide wire 2 which bridges the abdominal aorta 3 and the right iliac artery 4 are also illustrated. One end of these two guide wires 1, 2 exit the patient through the incision 8B in the right common femoral artery 4', and they are fed through a graft 10 (illustrated without stents). Specifically, guide wire 1 is fed through the opening at the first end 61 of the third hollow member 60 and then out through the first end 41 of the second hollow member 40. The second

guide wire 2 is fed through the first end 21 of the first hollow member 20 and then also out through the first end 41 of the second hollow member 40.

As illustrated in Figure 4, the present invention is advantageously used for endovascular surgery in connection with an abdominal aortic aneurysm. However, this technique can be used in any blood vessel and, in particular, any bifurcated blood vessel. For that reason, a bifurcated blood vessel will be referred to as having a first portion 3, a second portion 4 and a third portion 5, with the first portion, second portion and third portions all being joined in fluid communication with one another. When used in the context of abdominal aortic surgery, the first portion 3 of the blood vessel is the abdominal aorta, the second portion 4 of the blood vessel is the right or left iliac and/or femoral arteries and the third portion is the other iliac and/or femoral artery. It should also be apparent that while Figure 4 illustrates the feeding of the graft 10 onto guide wires 1 and 2 through the patients right iliac 4 and right femoral 4' arteries, it is equally possible to carry out the present invention through access 8C to the left iliac 5 and left common femoral 5' arteries. Similarly, introduction need not necessarily be through the iliac arteries or the common femoral arteries.

In one aspect of the present invention, a method is provided for introducing a bifurcated graft or bifurcated graft-stent assembly 10 into a bifurcated blood vessel. The method includes a step of providing a bifurcated graft 10', such as illustrated in Figure 1 and in particular, a graft-stent assembly 10 including a first hollow member 20, a second hollow member 40 and a third hollow member 60. Those hollow members are also in fluid communication with one another and each of the hollow members includes an opening at a first end 21, 41, and 61 respectively. Also disposed at each first end of each of the first, second and third hollow members are stents (not shown in Figure 4). At least one of the hollow

members and preferably, hollow members 20 and 60, are twisted prior to being introduced into the bifurcated blood vessel. In fact, both can be fed into the second portion 4 of the bifurcated blood vessel in a twisted orientation, although neither will remain therein. Once in place, the first hollow member 20 will be disposed within the first portion 3 of the blood vessel and the third hollow member 60 will be disposed within the third portion 5 of the blood vessel. As the first hollow member 20 and third hollow member 60 are positioned within the first and third portions of the bifurcated blood vessel respectively, the second hollow portion 40 of the graft-stent assembly 10 is pulled into the second portion 4 of the bifurcated blood vessel and resides therein when deployed. It is not necessary that the second hollow member be twisted before insertion into the second portion 4 of the bifurcated blood vessel. Thereafter, any twisted portions of the graft-stent assembly 10 are untwisted and the untwisted hollow members 20, 40 and 60 respectively are anchored in place by deploying the first, second and third stents (not shown in Figure 4). *See* Figure 20. Preferably, the graft-stent assembly 10 is fed over a plurality of guide wires 1 and 2 respectively, as previously described and as illustrated in Figure 4.

In a particularly preferred method, this procedure is accomplished in combination with the use of three mandrils which are designed to engage, retain, and restrain the stents located at the first ends 21, 41 and 61 of the first hollow member 20, second hollow member 40 and third hollow member 60 respectively.

In accordance with the present invention, the patient is placed supine on the operating table. A graphite table is recommended so that the patient can be fluoroscopically scanned from head to foot. Radiopaque rulers are placed behind the patient and optimum ruler positioning must be verified before the patient is prepped and draped. General or local

anesthetic with conscious sedation ("LMAC") anesthesia may be used with complete hemodynamic monitoring. An SV02 Swan Ganz catheter should be used for continuous SV02 (mixed venous O_2 saturation) and cardiac output monitoring is begun. Radial arterial lines should be inserted on the arm opposite the approach site to provide continuous monitoring of systolic as well as diastolic blood pressures. Cut downs are used to expose the left or right axillary artery and both common femoral arteries. The superficial femoral, as well as profunda femoral arteries are also exposed and controlled with vessel loops or umbilical tape.

A guide wire is then placed, initially beginning with the J guide wire, through a puncture 8A of the exposed left or right axillary artery, gaining access into the descending aorta 3 and down to the access femoral region 8B, at which point the guide wire is retrieved through a femoral arteriotomy. Direct injection of heparin saline into the femoral artery may be sufficient to maintain adequate anticoagulation for this part of the procedure but full systemic heparinization may also be initiated at this time. The use of floatation catheters to facilitate guide wire insertion would minimize contact with the aortic wall during insertion which would reduce the likelihood of dislodgment and immobilization of fragments of laminated thrombus. A second guide wire is now passed, beginning from the contralateral groin 8C into the distal aorta and retrieved either with grasping forceps, entrapment loops or by floatation guidance through the access groin femoral arteriotomy 8B.

Using exchange catheters, these wires are then replaced, with the operative guide wires 1 and 2 respectively. These operative guide wires are preferably .025" in diameter. However, their diameter can range from between about .014 to about .038 inches. The guide wires 1 and 2 are long enough to accommodate the full length of the mandril/sheath applicators, as well as the length of the graft-stent assembly

while still leaving some wire exposed at each end. The wires should be resheathed at each end to avoid contamination.

Once the operative guide wires 1 and 2 are in place, arteriotomies are made in the left axillary artery, as well as the femoral artery 5' opposite the access groin. An aortic occluding sheath can now pass over the guide wire coming down from the left or right axillary artery through access point 8A. The obturator is removed. If the patient is not already heparinized, he is given 10,000 units of heparin bolus and ACT determined in the next 3 to 5 minutes. A full aortogram is obtained through the aortic occluding sheath and is compared to the preoperative angiogram.

The appropriate graft-stent assembly 10 is then selected both by the length of the prosthesis, as well as the diameter of the stented portions. Assuming the right common femoral artery 4' is the access vessel, then a single lumen mandril 200 ("SLM") is now passed over guide wire 1 originating at the right femoral artery 4' and advanced in retrograde until the mandril 200 can be retrieved through the arterial cut-down 8C in the left common femoral artery 5'. A single lumen mandril 200 is illustrated in Figure 5. The single lumen mandril is so called because it has a single cavity 205 running through its entire length which is sufficiently large enough to accommodate a single guide wire, such as guide wire number 1. The SLM 200 slides over a guide wire and retains the stented portion of a graft-stent assembly, as will be discussed herein. As also discussed herein, the SLM as well as double lumen mandrils ("DLM"), allow the surgeon to easily advance a graft-stent assembly 10 into a bifurcated blood vessel and to accurately position and anchor that graft-stent assembly exactly where desired.

SLM 200 comprises a body 210 having a stent engaging end 212 and the housing or recess 216 disposed adjacent the stent engaging end

212 of body 210. SLM 200 also includes a second, generally tapered end 214 which is the leading end of the mandril when is fed through access point 8B as described. It is end 214 which is exposed and able to be manipulated through access 8C when in position. The SLM 200 is also provided with an associated sheath 400 which is shorter in length than SLM 200 and designed to move independently and axially along a portion of SLM 200, about its exterior.

As previously mentioned and as illustrated in Figures 6 and 7, SLM 200 is long enough to extend from outside of the cut down 8B in the patient's right groin through the right common femoral artery 4', through the right iliac artery 4, through the aortic divide at the base of the abdominal aorta 3, through the left iliac artery 5, the left common femoral artery 5' and out through the femoral cut down 8C in the left groin. In fact, SLM 200 can be long enough to extend for several feet on either side of its exit from the right and left femoral cut downs 8B and 8C respectively. Similarly, as illustrated in Figure 7, sheath 400 has a first end 402 adjacent the stent engaging end 212 of SLM 200 and a second end 404 generally disposed adjacent the extended tapered end 214 of SLM 200. Sheath 400 should be of a length which is also sufficient to allow it to extend out of the body from the groin cut downs 8B and 8C. However, as is also clear from Figure 7, sheath 400 is not as long as SLM 200.

As shown in Figures 4 and 8, the graft-stent assembly is brought onto the operative field and, maintaining the graft 10' in the appropriate orientation, guide wire 1 is fed through the third hollow member 60 and then out through the second hollow member 40 thereof. Guide wire 1 is coincidentally passed through stent 70 and stent 50 respectively. *See* Figure 8. See also Figure 9 illustrating the specific orientation of the first end 61 of the third hollow member 60 relative to guide wire 1 and SLM 200. As illustrated in Figure 8, this converts the

generally inverted "y"-shaped graft-stent assembly 10 (Figures 1 and 2) into the shape of an inverted "T".

If the access cut-downs and the arteries are sufficiently large, the stented graft assembly 10 can be inserted into the artery (in this case the second portion 4 of the blood vessel) without deformation, once attached to an SLM 200. However, when small arteries are used for access, or where otherwise necessary, it may be desirable in accordance with the present invention to wrap or twist the graft around the contained guide wires to reduce their profile. See Figure 10. The third hollow member 60 may be twisted in either clockwise or counter-clockwise direction. However, neither the stent 70 nor the radially expandable portion 63 of the third hollow member 60 should be twisted. Only the generally non-radially extendable portion 64 thereof should be twisted as illustrated.

As illustrated in Figures 9 through 12, the first end 61 of the third hollow member 60 containing stent 70 is advanced along guide wire 1 until stent 70 is in the proximity of the recess or housing 216 of SLM 200. Graft 70 is then collapsed, along with the expandable portion 63 of the third hollow member 60 around mandril 200 and specifically, within the mandrils housing 216. This may be accomplished in many ways, including the use of a manual compression pliar 250, as illustrated in Figure 11. The result is illustrated in Figure 12. Stent 70 is nested within the housing 216 of SLM 200.

Next, the first end 402 of sheath 400 is advanced over housing 216 so as to engage, restrain the expansion of, and retain the compressed stent 70 within. In fact, the first end 402 of sheath 400 is advanced such that it also, preferably, covers at least a portion of the untwisted portion of the radially expandable section 63 of third hollow

member 60. As best illustrated in Figures 13 and 14, stent 70 is thereby locked in a compressed position and can not move relative to SLM 200.

Gentle, careful traction is applied to the extended tapered end 214 of SLM 200 so as to advance the first end 61 of the third hollow member 60 as well as the stent engaging end 212 of SLM 200 through the access 8B to the second portion 4 of the bifurcated vessel. In terms of abdominal aortic surgery, when gentle traction is applied to SLM 200 as it exits the left groin, one of the extended limbs 60 of the graft-stent assembly 10 is pulled into the lumen of the right femoral and then right iliac artery. Subsequently, this portion of the graft-stent assembly will be moved into the distal aorta 3. Care should be taken not to bend the operative guide wire 1. It may be necessary to permit the stented portion of the graft to completely enter the second portion 4 of the bifurcated vessel before making a turn to enter the cross-over iliac artery 5. Sometimes the angle of aortic bifurcation is not wide enough to permit a 3 cm semirigid device to make the turn. One may therefore have to push the device further up the aorta which is wider to permit the turn. Manipulation of both ends of guide wire 1 will facilitate this maneuver.

Once the stented portion of the third hollow member 60 of graft-stent assembly 10 is within the proximal iliac artery 4, i.e., the second portion 4 of the bifurcated blood vessel, a second SLM 200', as well as a second sheath 400' is passed over guide wire 2 passing the extended tapered end 214' thereof over guide wire 2 and up through cut down 8B giving access to the second portion 4 of the bifurcated blood vessel. The extended tapered end 214' is then fed along guide wire 2 through the first portion of the bifurcated blood vessel 1. In the case of abdominal aortic surgery, extended tapered end 214' is retrieved through the axillary artery arteriotomy 8A. *See* Figure 4. The portion of guide wire 2 exiting the groin at the arteriotomy 8B is then passed into the first

hollow member 20 of the graft-stent assembly 10 as illustrated in Figures 4 and 15. The second guide wire 2 is also fed out of the graft-stent assembly 10 through the first end 41 of the second hollow member 40. As shown in Figure 16, it may be necessary or desirable to wrap or to twist the generally non-radially expandable portion 24 of the first hollow member 20, prior to compressing and restraining stent 30 about the housing 216' of second SLM 200'. Because this portion of the graft-stent assembly 10 is usually much shorter than the limbs (the second and third hollow members 40 and 60, respectively), it will take fewer turns to reduce same to its least possible diameter. Graft 30 is then compressed and locked into housing 216' of SLM 200' as was previously described for stent 70. The first portion 402' of the second sheath 400' is then advanced over housing 216' and over the compressed stent 30 and possibly the radially expandable portion 23 of the first hollow member 20 to maintain same in a restrained and compressed manor as previously described. *See* Figure 16. At this point, at least that portion of the first hollow member 20 mounted on SLM 200' can be fed in a retrograde fashion back into the second portion 4 of the bifurcated vessel. This can be accomplished by pulling on the extended tapered end 214' (not shown) which emanates through cut down 8A in the axiallary artery.

At this point, the entire bifurcated graft-stent assembly can be manipulated in place merely by manipulating mandrils 200 and 200'. This is particularly true if stent 50 located at the first end 41 of the second hollow member 40 were a balloon expandable stent. In that case, the stent would not need to be sheathed and no mandril would be needed. Of course, it would be possible to use a self-expanding stent and a sheath to prevent its expansion without using a mandril, although this is not a preferred method in accordance with the present invention. Specifically, the second hollow member can be pulled and fed into the second portion 4

of the bifurcated vessel. Should the second hollow member 40 become twisted during this operation, it could be repositioned using a conventional surgical device allowing the surgeon to grasp and manipulate same.

It is preferred, however, that the surgeon be provided with total control of each of the three hollow members. Since, according to the present invention, the mandrils are preferably only connected via the graft, this can be accomplished by the use of a third mandril assembly such as illustrated in Figure 17. The third mandril can be an SLM as previously discussed. For example, at this point the second guide wire 2 could be withdrawn from the patient through mandril 200' as the surgeon has control of that mandril through the extended portion 214'. Then, an SLM could merely be fed over guide wire 1 as previously discussed. It is also possible that guide wire 1 could be removed and a mandril used having no internal lumen. Of course, it is also possible that a single cavity or lumen be used. However, the use of a dual lumen would prevent any possibility of the wires entangling and, such a structure is therefore preferred.

Therefore, it is preferred that a double lumen mandril or DLM 300 be used. The DLM is substantially identical to the SLM and has a body 310 with a stent engaging end 312 an extended tapered end 314 and a housing or recess 316 for receiving and restraining a stent (in this case stent 50). DLM 300 also includes a sheath 400" having a first end 402" which is generally intended to cover the stent and a second end 404" which, when the graft-stent assembly is within the bifurcated blood vessel, will remain outside of the patient to allow for the independent movement of sheath 400". The one significant difference between the DLM 300 and SLMs 200 and 200' is the provision of two independent lumens or cavities 305 through which each of the individual guide wires 1 and 2 can be threaded.

In operation, the use of DLM 300 is substantially identical to that previously described in terms of the SLMs 200 and 200'. The stent engaging end 312 of DLM 300 is threaded over guide wires 1 and 2 and then advanced toward the stented end 41 of the second hollow member 40. Stent 50 is seated within the housing 316 and then compressed to reduce its size within housing 316. Then, the first end 402" of sheath 400" is advanced over the stent 50 and the radially expandable end 43 of second hollow member 40 to restrain same in a compressed configuration within the housing 316. Then, by pulling the extended tapered ends 214 and 214' of the mandrils 200 and 200', it is possible to guide the second hollow portion 40 and stent 50 of the graft-stent assembly 10 into position within the second portion 4 of the bifurcated vessel. *See* Figure 19. It is possible to twist the body 44 of the second hollow member 40 prior to restraining same in housing 316. However, it is generally unnecessary to do so.

As shown in Figure 19, the result is the positioning of the first hollow portion 20 of the graft-stent assembly 10 within the first portion 3 of the bifurcated vessel. The second hollow member 40 is disposed within the second portion of the bifurcated blood vessel 4 of the third hollow member 60 of the graft-stent assembly 10 is disposed within the third portion 5 of the bifurcated blood vessel. As shown in Figure 19, however, the first hollow member 20 and the second hollow member 60 are still at least partially twisted. The graft-stent assembly 10 can now be manipulated by the surgeon to place each hollow member exactly where it is necessary. This can be accomplished because of the ability of the surgeon to manipulate each of the various hollow members in a relatively independent manner by manipulating the individual mandrils 200, 200' and 300 at their extended tapered ends 214, 214' and 314.

Using a graft 10' as described previously in, for example, Figure 1, it is possible to manipulate not only the position of the graft, but also its axial or rotational orientation.

The axillary mandril 200' and sheath 400' are turned by the surgeon's manipulating and turning the extended tapered end 214' thereof. If the first hollow member 20 had been twisted in a clockwise direction, then a counter-clockwise motion is used to untwist same. Once all of the lines, markers, labels and/or lettering on the main shaft of the first hollow member 20 are in the appropriate position and orientation, it is possible to deploy stent 30. It is important to check not only the orientation of the various indicia, but also the space in-between the various lines and lettering to insure that defamation of the graft is avoided. It is also important to insure that the indicia 26 and 27, located adjacent the first end 21, of the first hollow member 20 are lined up exactly to the right and left of the aorta at the fixation point. If used, lines 29 should be straight and parallel and indicia such as lettering 28 should be in proper orientation and properly spaced. It is also important to insure that the proximal end 21 of the first hollow member 20 not be deployed such that it can block the feed of blood to and from the renal arteries although, the uncovered portion of stent 30 could extend into that junction. This can be accomplished using label or line 25.

Stent 30 can then be deployed by withdrawing or retracting sheath 400'. This is done by pulling on the second end 404' such that it moves independent toward end 214' of mandril 200' thereby exposing stent 30. Stent 30, when freed of sheath 400', will expand and anchor the first hollow member 20 in place within, for example, the abdominal aorta 3. The same procedure can be undertaken for the third hollow member 60, i.e., manipulation, untwisting, verification of its orientation and position. Thereafter, sheath 400 can be withdrawn over mandril 200 to free stent 70

to expand and implant within the left iliac artery 5. The process can then be repeated for the second hollow member 40 although, as this member is generally not intentionally twisted, less manipulation may be necessary. *See* Figure 20.

Of course, while this procedure has been described in terms of first positioning the first hollow member 20 and deploying stent 30, prior to further manipulation and deployment of, for example, the third hollow member 60, that order need not be maintained. For example, it may be desirable to completely untwist both the first hollow member 20 and the third hollow member 60, as well as adjust the position of the second hollow member 40 before any of the stents are deployed. The result, as illustrated in Figure 20, is a bifurcated graft-stent assembly 10 fully anchored in place, bridging an abdominal aneurysm or a similar defect in some other bifurcated blood vessel. The mandrils 200, 200' and 300 are now free of the graft-stent assembly and they can be withdrawn through access cut-downs 8A, 8B, and 8C, respectively. Guide wires 1 and 2 may also be withdrawn at this point, assuming they have not been withdrawn earlier.

One problem which may occur when performing any grafting procedure using a self-expanding stent is movement of the graft between the instant the sheath is withdrawn and the instant it expands and lodges into the wall of the vessel. This movement is caused by the current of blood through the vessel which carries the released and expanding self-expanding stent along with it. This phenomena is particularly troubling in terms of positioning the first hollow member 20 and stent 30. Adjustments may be made to compensate for this displacement by exposing the stent at a position which is slightly proximal to the area of the vessel into which the stent will actually sit. The blood flow would than carry the graft and stent into the proper position.

A more accurate way to accomplish proper placement is to stop blood flow through the vessel. Of course, this can be accomplished by conventional methods which temporarily stop the pumping of the heart. However, there are obvious risks to this procedure.

Alternatively, a balloon catheter can be used to occlude blood flow, for example, in the aorta. Such catheters are well-known. However, while such a device would be useful in connection with the prior art bifurcated grafts which are introduced through the iliac artery and which do not extend above the renal arteries, they would not be as useful with the present invention. In some preferred embodiments of the present invention, mandril 200' is used which must protrude above the junction of the abdominal aorta and the renal arteries. A conventional balloon occluding device would interfere therewith. Additionally, the conventional type of balloon catheter would not be useful when the mandril is to be inserted through, for example, the subclavian as it would occlude the artery and prevent removal of the sheath 400 from stent 30.

Of course, any method or device which can temporarily interrupt blood flow to allow for the placement of any stent, and in particular, self-expanding stents, which will not interfere with the operation of the apparatus of the present invention would be useful. One such apparatus is illustrated in Figures 21-23.

As illustrated in Figure 21, a balloon tipped occlusion device 5000 can be inserted into a blood vessel. The occlusion device 5000 is a hollow tube or sleeve 5010 having a proximal end 5021 and a distal end 5061. Preferably, an access chamber 5020, with or without a septum (not shown), may be disposed at the proximal end 5021 of the occlusion device 5000. The device 5000 and tube 5010 define a hollow cavity 5070 (see Figure 22) which extends from the access chamber 5020 through to an aperture 5060 disposed at the distal end 5061 of the occlusion device 5000.

Adjacent the proximal end 5021 of balloon tipped occlusion device 5000 is a gas inlet/outlet 5040 which is attached via tube 5030 to balloon 5050. Preferably, at least a portion of tube 5030 is disposed within the wall of sleeve 5010. Balloon 5050 is preferably disposed adjacent the distal and 5061 of occlusion device 5000. The placement of balloon 5050 is not important so long as it will rest in the intended blood vessel and stop the flow of blood when desired. A gas or liquid can be introduced through inlet/outlet 5040, through tube 5030 and into balloon 5050 to inflate same. Gas or liquid can also be withdrawn from balloon 5050 through tube 5030 and inlet/outlet 5040.

Tube 5010 is generally made from a flexible polymer or cloth material. This allows occlusion device 5000 to conform to the shape of the vessels in question thereby reducing surgical trauma. However, it is difficult to deploy such a pliable device. To assist the proper insertion and placement of occlusion device 5000, insertion catheter 5100 may be used.

As illustrated in Figure 23, insertion catheter 5100 comprises a body 5110 having a proximal end 5120 and a distal end 5130. In a preferred embodiment, the length of body 5110 is longer than the length of balloon occlusion device 5000. Insertion catheter 5100 is sized and shaped such that it can fit snugly within cavity 5070 of the occlusion device 5000 as illustrated in Figure 20. In a particularly preferred embodiment, proximal end 5130 of insertion catheter 5100 is tapered such that it will retain the distal end 5061 of occluding device 5000 and prevent same from sliding up body 5110 when the device is being delivered into a vessel.

Preferably, insertion catheter 5100 includes, at its proximal end 5120, a structure which allows it to nest and, preferably, substantially seal access chamber 5020. Insertion catheter 5100 also preferably includes one or more separate cavities, 5140 and/or 5150 through which may be fed

guide wires. This allows the occlusion device 5000 to be inserted into a blood vessel over the very guide wires which the mandril will travel.

In operation, the balloon tipped occlusion device 5000 is loaded onto insertion catheter 5100 such that the distal end 5130 of insertion catheter 5100 protrudes through the aperture 5060 at the distal end 5061 of the occlusion device 5000. Guide wire 2 is then threaded through cavity 5140 such that its free end protrudes through the proximal end of both the insertion catheter 5100 and the occlusion device 5000. Then, both the occlusion device 5000 and the insertion catheter 5100 are advanced along guide wire 2 into one or more blood vessels until such time as balloon 5050 is disposed in a position which will allow for the stoppage, or great reduction, of blood flow in the vessel in question. Placement of occlusion device 5000 also depends upon the disposition of aperture 5060 which must be positioned such that it is possible to deliver a bifurcated graft into the vessel in question there through. Then, insertion catheter 5100 can be withdrawn clearing aperture 5060 and passageway 5070 of the occlusion device 5000. A graft loaded on a continuous or discontinuous bifurcated delivery mandril can then be inserted over the guide wire, through an opening in the proximal end 5020 on the distal operative 5060 in occlusion device 5000 and fed through hollow cavity 5070 and finally out of occlusion device 5000. Once the graft is in place, balloon 5050 can be expanded by the introduction of fluid or air through inlet/outlet 5040, such that blood flow is temporarily interrupted. Then, for example, a self expanding stent 30 can be exposed such that it will expand radially, without any significant axially movement. Once the stent is lodged in the vessel, blood flow can be restored by deflating balloon 5050. These steps can then be repeated for a subsequent deployment of stents, as necessary.

Returning to the preferred method, in accordance with the present invention, the anesthesiologist again verifies the "ACT" (activated

clotting time) to make sure the patient is still fully anticoagulated. The aortic occluding balloon 5050 is then inflated, using half and half diluted contrast. *See* Figure 19. One-half to one atmosphere pressure within the balloon may be needed to achieve complete occlusion of the aorta. Prior to balloon inflation, the occluding catheter 5000 may have to be withdrawn a short distance to provide the at least 3 cm head room needed for stent 30's deployment. The proximal stent 30 is then deployed by slow, gradual withdrawal of the sheath 400' over the mandril housing 216'.

During deployment, minor adjustments of the positioning of the stent 30 or the proximal end 21 of the graft 10 may be needed by comparison with the ruler markings demonstrating the location of the renal arteries. When necessary, the uncovered portion of the stent 30 may be deployed at or above the renal arteries. However, the covered portion of the stent must not be proximal to the renal artery orifices. Similarly, the uncovered distal stents 50 and 70 may be deployed across the hypogastric artery orifices. Once the proximal stent 30 is deployed, flow is gradually restored into the aorta and the graft 10 by gradual deflation of the aortic occlusion balloon 5050. This will permit blood to flow to fill the graft 10 material down to the tip of the iliac mandril sheath assemblies 200 and 300. The aortic occluding balloon 5050 is again temporarily inflated. Assuming that the third hollow portion 60 of the graft 10 has remained in its appropriate orientation, deployment may follow on the side opposite the access femoral artery, again by withdrawing the sheath 400 over the mandril housing 216. The mandril sheath assembly may now be removed through the contralateral femoral arteriotomy. The aortic occluding balloon is now deflated. With the distal common femoral artery occluded, free bleeding is now permitted for a few seconds to flush out all loose debris and possibly air pockets through the arteriotomy before restoring flow into the distal extremity following closure of the femoral arteriotomy.

Prior to deployment of the third hollow member 60 of graft stent assembly 10, the surgeon may choose to gradually withdraw the guide wire 1 into the cross-over limb until it is in the straight portion of the graft 10 and then either advance it into the proximal aorta or leave it in place in the limb, in case impaction of the stent with a balloon is needed. Deployment of the right limb or second hollow member 40 of the graft 10 is performed in a similar fashion and the mandril sheath assembly 300/400" on that side retrieved through the right femoral arteriotomy 8B. Completion aortography is then obtained, again through the aortic occluding sheath, which now also contains the mandril sheath assembly for the proximal stent. Once the arteriogram is completed, the aortic occluding sheath is withdrawn together with the mandril sheath assembly. The axillary arteriotomy is also closed, following removal of the guide wires.

It may be necessary to have the bilateral radial lines in place throughout the procedure, in order to be certain that no gradient has been created by all of the procedures through the chosen axillary artery. If the left and right axillary arteries are occluded, any of the brachiocephalic vessels may be used for this retrieval of the mandril sheath, including the right or left carotid arteries.

The compressing of self-extending stents into the housing of a single or double lumen mandril, in accordance with the present invention, can be accomplished manually or by using any suitable device including a pliar, a band or tightened belt and the like. One particularly advantageous device is illustrated in Figures 11 and 24. The compression tool 250 is similar to a pliar or scissors and comprises opposable arms 251 and 252, which are joined at a pivot point 253, such that when the first ends 258 and 259 thereof are spread apart, the second ends 257 and 256 respectively, are spread apart as well. A spring 254 can be attached to one or more of the

arms to bias the action of arms 251 and 252 about pivot point 253 to provide greater control. Single loops can be located at the second ends 258 and 259, as shown in Figure 24. As shown best in Figure 11, device 250 will have a certain width. The width of the second ends 256 and 257, which will engage the self-expanding stent to compress same may have an even greater width. This allows the compressive force of the tool to be spread out along a greater distance of the stent when applied. Most preferably, the second ends 256 and 257 will also include a structure such as a hemispheric groove, which will assist in accommodating the stent and compressing it into a compressed position such that uniform compressive force can be applied thereto. Automated compressive devices could be used as well, particularly when the surgeon will be provided with a pre-packaged graft-stent assembly 10, already associated with a plurality of mandrils.

Sheath 400 (and 400', 400"), in accordance with the present invention, can be made from any material conventionally used. These include woven and non-woven fabrics mono-layer or multi-layer polymers, metals and the like. Sheaths are currently commercially available. There is some concern, however, that when the graft 10' becomes wetted by blood, it will make it more difficult to withdraw the first ends 402, 402', 402" of sheaths 400, 400', 400" from the housings 216, 216' and 316 respectively, so as to allow for the exposure and expansion of stents 30, 50 and 70, respectively. There are several ways of dealing with this problem.

First, materials used for the sheath and/or the mandrils can be selected to have a particularly low coefficient of friction. Alternatively, the inner surface of sheath 400, 400', 400" particularly that portion of it adjacent the first end 402, 402', 402" thereof, can be coated with a material which has a low coefficient of friction such as Teflon. Alternatively, it may be possible to overcome this problem, if any, by

producing a graft made from a material which either does not wet immediately or has a low coefficient of friction when wetted. Coating the surface of the sheath, graft or even the mandril with a material such as Teflon, i.e. any material with a relatively low coefficient of friction, will also work.

Another alternative is the use of a perforated sheath, i.e., a sheath having perforations at its first ends 402, 402' and 402". When pressure is applied such as when withdrawing the sheath, the perforations can tear and thereby allow the stent to expand, freeing the stent and the sheath from the mandril.

Another possible approach is illustrated in Figures 25, 26 and 27. As illustrated in Figure 25, sheath 400 is actually composed of two sheaths, one disposed within the other. The inner sheath 420 can be made of, for example, a more rigid polyurethane. The majority of the length of inner sheath 420 is a substantially cylindrical body 422 and extends from the vicinity of the mandril housing 216 through to the extended tapering portion 214 of the mandril. At the extreme end thereof, adjacent the mandril housing, are located a number of somewhat rigid protuberances, projections or fingers 424. These fingers 424, when slipped over a graft and stent compressed into housing 216, are of sufficient rigidity to maintain the graft and sheath within housing 216 of mandril 200 in a generally compacted position. Of course, when a self-expanding stent is used, that stent is, in essence, a spring and some re-expansion may occur.

Surrounding this first sheath 420 is a second sheath 430 which can be made from the same or a different material. Again, it is preferable that the material used for this sheath have a particularly low coefficient of friction or be coated or at least its inner surface with a low friction material such as Teflon. The outer sheath can also be made of, for example, a metal alloy. The inner sheath 420 and the outer sheath 430 are

movable relative to each other and axially relative to the mandril 200. Once the graft and stent have been seated in the housing 216, inner sheath 420 can be advanced to cover the housing as illustrated in Figure 26. The outer or second sheath 430 can also be advanced in the same direction so as to cover not only the housing, but also the advanced fingers 424 of inner sheath 420. As shown in Figure 27, the result is that outer sheath 430 will completely cover the inner sheath 420 as well as completely covering the housing 216 of the mandril 200.

In this configuration, the first end 402 of at least the outer sheath 430, will be adjacent the stent-engaging end 212 of mandril 200. While described in terms of mandril 200, the same configuration of inner and outer sheath can be used in combination with the other SLM and DLM mandrils discussed herein.

To release a stent contained within the housing by the composite sheath 400, both the inner sheath 420 and the outer sheath 430 can be manipulated from outside the body of the patient such that they travel along the mandril toward the extended tapered end 214 thereof. Alternatively, the outer sheath can be moved independently of the inner sheath and, once the inner sheath is fully exposed in the area of the housing 216, the inner sheath can be moved as well. To accomplish this type of deployment, it is generally useful to insure that the inner sheath 420 is longer than the outer sheath 430, such that even when the outer sheath 430 is retracted, a sufficient portion of the inner sheath 420 is exposed at the second end of the sheath 404 adjacent the extended tapering end 214 of mandril 200 so as to allow the inner sheath to be independently manipulated.

When using this type of sheath construct it is particularly advantageous to use a locking mechanism 450 which allows for precise control of each of the individual sheaths for locking device 450 should

engage the mandril 200. These locking devices are generally not permanently attached to the extended tapered end 214 and mandril 200 and instead can be slipped over the extended tapered end 214 thereof once the mandril has been fed through a portion of the bifurcated vessel. The locking device includes two members which are slidable relative to one another. As illustrated, member 470 engages the extended tapered portion 214 of mandril 200, while a separate element 460 engages the outer sheath 430 and not necessarily the inner sheath 420.

It is preferable that the locking device is attached after the inner and outer sheath have already been advanced to a position whereby they retain the graft-stent in the housing of the mandril. *See* Figure 27. The locking device is therefore in its extended position as shown in Figure 27. By allowing the locking device to return to its retracted position, it engages and retracts the outer sheath 430 to expose the finger-like projections 424 of the inner sheath 420. As the outer sheath is retracted further, it abuts a shoulder 421 disposed at the end of the inner sheath 420 and begins to retract the inner sheath as well. This locking device also helps prevent rotation and twisting of the mandril relative to the sheath. Any other locking device may also be used to help prevent the rotation of the mandril and the sheaths relative to each of the sheaths is also contemplated.

The locking device 450 can also be used with a conventional single-layer sheath system. As illustrated in Figures 28 and 29, the elimination of the inner sheath and the shoulder means that when the device 450 is returned to the retracted position illustrated in Figure 29, slidable member 460 which engages the sheath 400 adjacent its second end 404, is urged in the direction of the extended tapered end 214 of mandril 200. It then exposes the housing 216. The lower slidable member 470 is anchored to the extended tapered end 214 of mandril 200 to prevent the

sheath from moving independently of the mandril until it is time to expose the stent contained in housing 216.

Another alternative can be used in place of the inner and outer sheath arrangement just described. As shown in Figures 30-34, it is possible to construct an outer sheath which contains an inner sheath or inner collar 480. The inner collar 480 can be formed of a solid polymer material, just like the inner sheath 420 previously described and can be composed of a number of finger-like projections 482 which are sufficiently rigid to restrain the graft-sheath assembly in the mandril housing 216 to some degree. This collar can be fitted with a number of guide pins 484 which can themselves fit cooperatively into a number of grooves or guides 435 contained in the outer sheath 430 to allow the collar 480 limited range of motion forward and backward relative to the sheath 400 itself. In use, a sheath 400 including collar 480 would be advanced over the mandril 200 toward housing 216. Then, the collar 480 would be advanced over the compressed stent and graft to retain same within the housing 216. Again, some expansion of the stent, particularly if it is a self-expanding stent, can be anticipated despite the rigidity and resilience of the finger-like projections 482. Of course, it is also possible to design a system so that rigid control would be maintained over the compressed stent. Then the outer sheath 430 can be advanced to cover both the collar 480 and the graft-stent assemblies in the housing 216. As the outer sheath 430 is advanced, the guide pin 484 traverse the distance of groove or guides 435 traveling from one end to the other.

When it is time to deploy the graft-stent assembly, the outer sheath 430 is retracted. However, because of the friction between the collar 480 and the graft and stent located in the housing 216, the collar 480 may remain substantially in place. Once guide pins 484 have reached the forward end walls of guides 435 contained within the wall of the outer

sheath 430, further retraction of the outer sheath 430 will also cause the retraction of the collar 480 as well. Once collar 480 is retracted from over housing 216, the graft-stent contained therein is free to expand and embed within the vessel.

The use of guide pins 484 and guides 435 is but one possible way of accomplishing this aspect of the invention. In fact, anything which will allow the collar a selected range of movement is contemplated. For example, a series of channels could be provided within the inner surface of the outer sheath 430 while shoulders provided at the end of collar 480 should be provided to stop the forward and backward movement of the collar 480 and each could be provided with a locating group to prevent substantial rotational movement of the collar relative to the sheath.

This sheath/collar assembly can also be used with the retraction/locking member 450 as previously discussed. As slidable member 470 is retracted towards member 460, it will retract the outer sheath 430. Eventually, the outer sheath 430 will be retracted sufficiently such that the pins 484 will engage the end wall of groove 435 and further retraction of the outer sheath will also cause retraction of collar 480 as well.

In another embodiment, the sheath can be constructed with an embedded rip-cord which will trail out of the body. When it is necessary to withdraw the stent, the rip-cord can be pulled and that will break the sheath and allow it to be pulled away.

Of course, it is also possible to use balloon expandable stents 30, 50 and 70 instead of self-expanding stents as described herein. The use of balloon expandable stents is made all the more practical when endovascular surgery, in accordance with the present invention, is performed using a vascular band, as described herein. In this case, it may be possible to provide within the housing 216 of mandril 200, for example,

a balloon. Access may be provided through a tube integrally formed within mandril 200, which allows a liquid or gas to be pumped into the balloon to expand same when necessary. The use of a balloon expandable stent, if it can be collapsed sufficiently tightly within housing 216, may illuminate the need for a sheath 400 entirely. However, it may be desirable to use sheaths as previously described. A combination of self-expanding and balloon expandable stents are also useful in accordance with the present invention.

As previously discussed, one problem which has limited the general applicability of endovascular surgery, particularly to younger patients, is the problem of the expansion of blood vessels as the patient ages. As described herein, that problem can be overcome by one aspect of the present invention.

In accordance with this aspect of the present invention, a retaining band is placed around the exterior of the blood vessel and over either the stent, or that portion of the vessel in which the stent will be deployed. Thus, banding can occur either before or after a stent is deployed. The band will effectively stop the expansion of the vessel in the region of the stent and will provide an ideal anchoring surface. In a particularly preferred aspect of the present invention, these vascular bands are provided to the patient in a laparoscopic procedure which can be undertaken before, during or even years after endovascular surgery. It is important to note that the vascular bands and methods of use as discussed herein may be used in conjunction with the endovascular devices and methods also described herein. They may also be used in combination with any other endovascular surgical technique or any time a blood vessel needs to be wrapped permanently.

In the practice of one aspect of the present invention, about a 3 cm segment 6 of the abdominal aorta 3 immediately distal to the renal

arteries 150 and 151 is exposed using video-laparoscopic techniques through a left lateral extraperitoneal approach. Careful circumferential dissection of the aortic neck 6 is then performed. *See* Figure 35. This ensures that the band can be manipulated around the abdominal aorta 3 without interference.

Generally, the band 1000 is introduced into the operative field through one of the laparoscopic operative ports or trocars. In a preferred embodiment, the band 1000 is designed to be clearly visible fluoroscopically because of radiopaque lines disposed, for example, longitudinally within the woven fabric. In addition, indicia such as centimeter and millimeter marks are disposed along both edges on both major surfaces of the band 1000. These may be composed of radiopaque and/or non-radiopaque materials, inks, dyes, etc. *See* Figure 36.

A right angle dissection device is passed around the aorta posteriorly or behind the aorta. The free end of the band 1000 is grasped and pulled through and under the previously dissected space behind the aorta. Enough of the band is pulled through such that one end of the band is about 1 cm anterior the aorto-caval groove. The band 1000 is then joined at the point corresponding to the calculated circumference of the infra-renal aortic neck. The circumference of the aortic neck is equal to $\Pi \times D$ where D is the diameter of the aorta as measured by aortogram. The excess band 1000, if any, is amputated and removed through the trocar.

Band 1000 is made of flexible, generally non-elastic, non-absorbable material. Therefore, this procedure will result in a fixed diameter aortic neck into which the proximal stent of a stent or graft stent assembly may be fitted without fear of further aortic expansion or stent/aorta separation and leakage at this point of fixation. The same techniques should be applicable at it iliac ends. The ultimate aim is to

make the endovascular approach to aortic replacement applicable even in relative young patients in whom long term survival is expected.

As should be readily apparent from the above general discussion, band 1000 can be applied to the blood vessel prior to endovascular surgery to provide a better surface for deploying the stent and/or, to assist in preventing the rupture of the aneurysm. Alternatively, the surgical procedure to affix the bands in accordance with the present invention can be conducted immediately following endovascular surgery once the graft has been put in place and secured by deploying either a self-expanding or a balloon-extendible stent. Finally, the procedures in accordance with the present invention can be done years after endovascular surgery either to prevent leakage, or as a method of stopping leakage once the vessel wall has expanded.

It is not essential that banding in accordance with the present invention be conducted laparoscopically. In fact, it is possible to expose the abdominal aorta and the iliac arteries, where appropriate, and apply the bands in a traditional surgical fashion. However, it is easier on both patient and surgeon to perform the procedure laparoscopically, as described above.

The general techniques for conducting laparoscopic surgery are known as retroperitical laparoscopic gas or gasless techniques. *See* 9 Y.M. DION, A.U. CHIN & T.A. THOMPSON, *Experimental Laparoscopic Aortobifemoral Bypass*, SURGICAL ENDOSCOPY (1995) 894-97 and 1 A.K. CHIN, *Mechanical Peritoneal Retraction as a Replacement for Carbon Dioxide Pneumoperitoneum*, JOURNAL OF THE AMERICAN ASSOCIATION OF GYNECOLOGIC LAPAROSCOPY (No. 1. 1993). Generally, however, one or more trocars are inserted into the patient adjacent the location of the stents of the bifurcated graft in the aorta and the iliac arteries. Limiting discussion only to the abdominal aorta for the time being, the surgeon

would carefully ensure that the abdominal aorta 6 surrounding the stent 30 is isolated such that band 1000 or other similar device can be wrapped around same. Band 1000 is then inserted through a catheter or trocar into the cavity created laparoscopically in the abdomen. In one embodiment, band 1000 may be rolled longitudinally to be inserted through a trocar, trailing the sutures 1007 behind. Once band 1000 clears the trocar and has entered the abdominal cavity, it is unfurled. As shown in Figure 36, band 1000 is then grabbed at a first end 1002 and fed underneath the abdominal aorta 3 beneath the junction with the renal arteries 4. Band 1000 is, in this case, made from a generally woven fibrous material such that it is possible to perforate same with the relatively blunt metal sutures needles 1005. Suturing needles 1005 are attached to the second end 1006 of band 1000 through sutures 1007. The sutures 1007 may then be threaded through the band 1000, as illustrated in Figure 37. Band 1000 may additionally be provided with a plurality of already spaced holes, in order to allow an even more convenient means of threading the suture needles 1005 and sutures 1007 therethrough. In addition, band 1000 preferably has indicia 1111, on both of its major surfaces 1008 and 1009 which are preferably readable under a fluoroscope. Since the surgeon has precalculated the circumference of the stent and vessel, these indicia 1111, equally spaced by a number of millimeters or centimeters, can assist the surgeon in forming band 1000 of the proper circumference. For the same reason, a plurality of lines 1112 or a grid pattern is also useful if formed on the first and second major surfaces 1008 and 1009, respectively. Whether through pre-provided holes or through perforation of the band with suture needles 1005, the suture needles 1005 and sutures 1007 are then passed through band 1000 as illustrated in Figure 37 at a position which is sufficient to allow for the formation of band 1000 which will snugly engage the abdominal aorta and possibly a portion of the graft

and/or stent. Once all of the sutures 1007 A, B, C and D have been fed through band 1000, they can be tied together as shown in Figure 38. This completes the band by bringing the secured second end 1006 of band 1000 into contact with another portion of band 1000 and fixes band 1000 in place. As illustrated in Figure 38, sutures 1007A and 1007B are tied together and sutures 1007C and 1007D are tied together to retain band 1000 in close contact with the abdominal aorta 6. Finally, as shown in Figure 39, the excess of the band 1000 material can be cut away and removed through a trocar.

It is important to restrain the outward expansion or growth of the blood vessel. However, it is equally important to insure that sufficient blood flows to the wall of the vessel to insure that it does not become diseased or die. Therefore, as illustrated in Figure 40, it is possible to use a wrap or band 1000 made of a sheet of material which defines a plurality of apertures 1130 which leave exposed large portions of the exterior surface of the vessel when the device is wrapped around same. The vessel and other tissue can grow and develop into these wholes or apertures 1130 which helps anchor the material in place and promotes the health of the vessel.

This could be a perforated sheet or a sheet of material which is more akin to a web or netting. These apertures 1130, which are defined within the band, generally will have a length, width or diameter, as appropriate, of at least about 1mm. Most preferably, the apertures will have a width of at least about 2mm.

Also, as illustrated in Figure 40, sutures need not be the connector used in accordance with the present invention as previously described. In fact, the fastener or connector can include one or more hooks 1120 which can engage one of the apertures, a hook and a plurality of loops or a second band of greater diameter wrapped around the first

band and tied in place. In fact, using a string or suture 1121, it may be possible to connect the two ends of the band to complete the encirclement of the vessel. Suture 1121 can be tied completely around the band 1000, like tying up a rolled up newspaper. Alternatively, with the perforated web shown in Figure 40, one can also just tie the two ends of the web together by threading the suture 1121 through apertures 1130 at both ends of the sheet.

In addition, the inner surface 1009 and outer surface 1008 of band 1000 can be provided with cooperative Velcro-like fastener such that the band can be wrapped around the abdominal aorta and attached as the attachment means on the inner surface 1009 as wrapped over top of the end 1006 of the outer surface thereof. The remainder can then be cut away.

Band 1000 can be made of any flexible, resilient, non-elastic material conventionally used in surgery. In fact, it can be made of the same materials conventionally used for non-dissolvable sutures and/or for grafts. The material must be flexible and somewhat pliant. However, when in fixed position, it should maintain that position and prevent the further expansion of the vessel and the stent. The material used is generally woven, but non-woven material, for example, polymeric or rubber sleets, may also be used.

It is also possible to use a band which does not include sutures 1007 and suture needles 1005 or another form of connector. In that case, the band must be sutured or otherwise caused to adhere to itself and/or the aorta. The ends of the band could be sutured manually, or by use of a suturing device such as the ENDOSTITCH from U.S. Surgical. In this eventuality, for example, the band can merely be wrapped or folded around the vessel, until various portions of the inner major surface of the

band meet. Those ends can then be sutured together at the point of contact and the excess material from both ends of the band dissected and removed.

The foregoing has been described generally in terms of a bifurcated graft used in treating an abdominal aortic aneurysm. However, the same laparoscopic banding technique can be used on a non-bifurcated graft, as well as for treatment of vessels other than the abdominal aorta or the iliac arteries. For example, a band in accordance with the present invention could be laparoscopically placed around a puncture in a vein or artery to assist in sealing same.

INDUSTRIAL APPLICABILITY

The invention relates to the medical and surgical industries and provides techniques and articles to be used surgically. The production of such devices and dissemination of such information also have application to medical products manufacturers.

Claims:

1. A graft useful in endovascular surgery comprising: at least one hollow member for placement into a blood vessel, said at least one hollow member having a first end, a second end and an extended portion therebetween and, said at least one hollow member having indicia disposed in association with said first end which is indicative of the location of said first end of said at least one hollow member when said at least one hollow member is placed into a blood vessel during surgery.

2. The graft of claim 1, further comprising indicia associated with said second end of said at least one hollow member which is indicative of the location of said second end of said at least one hollow member when said at least one hollow member is placed into a blood vessel during surgery.

3. The graft of claim 1, wherein said at least one hollow member comprises a first hollow member and wherein said graft further comprises a second hollow member for placement into a blood vessel, said second hollow member having a first end, a second end and an extended portion therebetween, and said second hollow member having indicia disposed in association with said first end which is indicative of the location of said first end of said second hollow member when said second hollow member is placed into a blood vessel during surgery, said second end of said first hollow member and said second end of said second hollow member being joined such that said first hollow member and said second hollow member are in fluid communication.

4. The graft of claim 3 wherein said indicia also serves as an indication of the axial orientation of said ends of said hollow members.

5. The graft of claim 3, further comprising indicia which can serve as an indicator of the axial orientation of portions of said hollow

members within a vessel during surgery, said indicia being arranged adjacent said first ends of said hollow members.

6. The graft of claim 3, further comprising indicia which can serve as an indicator of at least the axial orientation of portions of said hollow members within a vessel during surgery, said indicia being disposed on said extended portions of said first and said second hollow members.

7. The graft of claim 3, further comprising indicia which can serve as an indicator of the axial orientation of portions of said hollow members within a vessel during surgery, said indicia being arranged adjacent said first ends of said hollow members and indicia which can serve as an indicator of at least the axial orientation of other portions of said hollow members within a vessel during surgery, said indicia being disposed on said extended portions of said first and said second hollow members.

8. The graft of claim 1, wherein said indicia is radiopaque.

9. The graft of claim 3, wherein said indicia is radiopaque.

10. The graft of claim 7, wherein said indicia is radiopaque.

11. The graft of claim 3, further comprising a third hollow member, said third hollow member having a first end, a second end and an extended portion therebetween and said third hollow member having indicia disposed in association with said first end which is indicative of the location of said first end of said third hollow member when said third hollow member is placed into a blood vessel during surgery, said second end of said first, second and third hollow members being joined such that they are in fluid communication.

12. The graft of claim 11, further comprising indicia which can serve as an indicator of the axial orientation of portions of said hollow members within a blood vessel during surgery, said indicia being arranged adjacent said first ends of said hollow members.

13. The graft of claim 11, further comprising indicia which can serve as an indicator of at least the axial orientation of portions of said hollow members within a vessel during surgery, said indicia being disposed on said extended portions of said first hollow member and said second hollow member and said third hollow member.

14. The graft of claim 11, further comprising indicia which can serve as an indicator of the axial orientation of portions of said hollow members within a vessel during surgery, said indicia being arranged adjacent said first ends of said hollow members and indicia which can serve as an indicator of at least the axial orientation of other portions of said hollow members within a vessel during surgery, said indicia being disposed on said extended portions of said first and said second hollow members.

15. The graft of claim 11, wherein said indicia is radiopaque.

16. The graft of claim 3, further comprising a stent attached to said first ends of said first and said second hollow members.

17. The graft of claim 10, further comprising a stent attached to said first end of said first hollow member, said second hollow member and said third hollow member.

18. A method of introducing a bifurcated graft into a bifurcated blood vessel, said blood vessel having a first portion, a second portion and a third portion, said first, second and third portions all being joined and in fluid communication, comprising the steps of:

providing a bifurcated graft-stent assembly including a first hollow member having an opening at a first end thereof and a fist stent disposed within said opening, a second hollow member having an opening at a first end thereof and a second stent disposed within said opening and a third hollow member having an opening at a first end thereof and a third stent disposed within said opening, said first hollow member, said second hollow member and said third hollow member being joined and in fluid communication with each other;

feeding a first mandril into said bifurcated vessel such that said first mandril bridges said second and said third portions of said vessel and releasably retaining said first end of said third hollow member and said third stent to a first mandril;

inserting at least said first end of said third hollow member and said third stent into said second portion of said vessel;

feeding a second mandril into said bifurcated vessel such that said second mandril bridges said first and said second portions of said vessel and releasably retaining said first end of said first hollow member and said first stent to said second mandril;

inserting at least said first end of said first hollow member and said first stent into said second portion of said vessel; and

feeding at least at least a portion of said second hollow member into said second portion of said vessel.

19. The method of claim 18 further comprising the step of providing a third mandril and releasably retaining said first end of said second hollow member and said second stent thereto prior to said step of feeding at least a portion of said second hollow member and said second stent into said second portion of said vessel.

20. The method of claim 19 further comprising the steps of manipulating said bifurcated graft-stent assembly such that said first

hollow member and at least a part of said second mandril are disposed within said first portion of said vessel, said third hollow member and at least a part of said first mandril are disposed within said third portion of said vessel, and said second hollow member and at least a part of said third mandril are disposed within said second portion of said vessel;

releasing said first end of said first hollow member and expanding said first stent to anchor said first hollow member within said first portion of said vessel;

releasing said first end of said second hollow member and expanding said second stent to anchor said second hollow member within said second portion of said vessel;

releasing said first end of said third hollow member and expanding said third stent to anchor said third hollow member within said third portion of said vessel; and

withdrawing said first mandril from said first portion of said vessel, said second mandril from said second portion of said vessel, and said third mandril from said third portion of said vessel.

21. The method of claim 18, further comprising the step of twisting said third hollow member prior to feeding at least said first end of said third hollow member into said second portion of said vessel.

22. The method of claim 21, further comprising the step of twisting said third hollow member prior to releasably attaching said first end of said third hollow member to said first mandril.

23. The method of claim 18, further comprising the step of twisting said first hollow member prior to feeding at least said first end of said first hollow member into said second portion of said vessel.

24. The method of claim 23, further comprising the step of twisting said first hollow member prior to releasably attaching said first end of said first hollow member to said second mandril.

25. The method of claim 21, further comprising the step of untwisting said third hollow member prior to said step of releasing said first end of said third hollow member and expanding said third stent to anchor said third hollow member within said third portion of said vessel.

26. The method of claim 25, further comprising the step of verifying that said third hollow member is untwisted prior to said step of releasing said first end of said third hollow member and expanding said third stent to anchor said third hollow member within said third portion of said vessel.

27. The method of claim 23, further comprising the step of untwisting said first hollow member prior to said step of releasing said first end of said first hollow member and expanding said first stent to anchor said first hollow member within said first portion of said vessel.

28. The method of claim 27, further comprising the step of verifying that said first hollow member is untwisted prior to said step of releasing said first end of said first hollow member and expanding said first stent to anchor said first hollow member within said first portion of said vessel.

The method of claim 18 further comprising the steps of providing a first guide wire having a first end and a second end, said first guide wire bridging said second and said third portions of said vessel;

providing a second guide wire having a first end and a second end, said second guide wire bridging said first and said second portions of said vessel;

threading said first guide wire through a cavity in said first mandril and through said third and second hollow members of said graft-stent assembly prior to releasably retaining said first end of said third hollow member and said third stent to said first mandril; and

threading said second guide wire through a cavity in said second mandril and through said first and said second hollow members of said graft-stent assembly prior to releasably retaining said first end of said first hollow member and said first stent to said second mandril

29. A method of introducing a graft into a blood vessel comprising the steps of:

providing a graft-stent assembly including at least one hollow member, said at least one hollow member including an opening at a first end thereof and further including a stent, disposed within said opening;

twisting said at least one hollow member prior to feeding at least said first end of said first hollow member into a portion of said blood vessel;

feeding at least said first end of said twisted at least one hollow member into said blood vessel;

untwisting said at least one hollow member; and

anchoring said at least one hollow member within said vessel.

30. The method of claim 29, further comprising the step of verifying that said at least one hollow member is untwisted prior to said step of anchoring said at least one hollow member within said vessel.

31. The method of claim 30 further comprising the step of checking the position and the axial orientation of said at least one hollow member prior to said step of anchoring said at least one hollow member within said vessel by reviewing the position and axial orientation radiopaque indicia which is associated with said at least one hollow member.

32. The method of claims 30 or 31 wherein said at least one hollow member is a first hollow member and the associated stent is a

first stent, and wherein said graft includes at least a second hollow member joined in fluid communication with said first hollow member, said second hollow member including an opening at a first end thereof and further including a second stent, disposed within said opening.

33. The method of claim 32 further comprising the step of twisting a portion of said second hollow member prior to feeding same into said vessel; feeding at least a portion of said twisted second hollow member into said vessel; untwisting said second hollow member; and anchoring said second hollow member within said vessel

34. The method of claim 33, further comprising the step of verifying that said twisted second hollow member is untwisted prior to said step of anchoring said second hollow member within said vessel.

35. The method of claim 34 further comprising the step of checking the position and the axial orientation of said at second hollow member prior to said step of anchoring said at second hollow member within said vessel by reviewing the position and axial orientation of radiopaque indicia which is associated with said second hollow member.

36. A bifurcated graft-stent assembly comprising: including a first hollow member including an opening at a first end thereof and further including a first stent attached within said opening, a second hollow member including an opening at a first end thereof and further including a second stent attached within said opening and third hollow member including an opening at a first end thereof and further including a third stent attached within said opening, said hollow members being joined and in fluid communication with each other, at least one of said hollow members further comprising indicia disposed in association with said first end thereof which can indicate the position of said first end of said hollow member when disposed within a blood vessel.

37. The bifurcated graft-stent assembly of claim 36 further comprising indicia disposed along said at least one hollow member which can indicate the axial orientation of said hollow member when disposed within a blood vessel.

38. A device for the delivery of a bifurcated graft during endovascular surgery comprising: A bifurcated graft-stent assembly comprising: including a first hollow member including an opening at a first end thereof and further including a first stent attached within said opening, a second hollow member including an opening at a first end thereof and further including a second stent attached within said opening and third hollow member including an opening at a first end thereof and further including a third stent attached within said opening, said hollow members being joined and in fluid communication with each other, said first and said third hollow members and said first and said third stents being releasably retained in contact with a single lumen mandril and said second hollow member and said second stent being releasably retained in contact with a dual lumen mandril;.

39. The device for the delivery of a bifurcated graft during endovascular surgery of claim 39 further comprising indicia disposed in association with said first end at least one of said hollow members which can indicate the position of said first end of said hollow member when disposed member is twisted when disposed within a blood vessel.

40. A device for wrapping around a length of a blood vessel comprising:

A sheet having a first end, a second end and a body extending therebetween, a connector for joining one portion of said body to a second portion of so as to form a closed band, said sheet being sized and shaped to allow it to be introduced into operative proximity of a blood vessel laparoscopically and being composed of a material which is

medically inert, sufficiently flexible to allow manipulation and resilient enough to resist the expansion of the vessel.

41. The device of claim 40 wherein said sheet has a structure which will minimize tissue devascularization.

42. The device of claim 41 wherein said sheet is composed of a material which defines a plurality of apertures which leave exposed the exterior surface of a vessel when the device is wrapped around same.

43. The device of claim 42, wherein said apertures are at least about 1 mm.

44. The device of claim 43, wherein said apertures are at least about 2 mm.

45. The device of claim 40 wherein said connector is selected from the group consisting of at least one suture, at least one snap closure, at least one hook, a hook and loop fastener, and a second band of greater diameter.

46. The device of claim 40 further comprising radiopaque indicia.

47. A device for wrapping around a length of a blood vessel comprising:

A sheet having a first end, a second end and a body therebetween, said sheet having a width of at least about 2.0 cm, a connector for joining at least one portion of said body to a second portion of said body so as to form a closed band, said connector being selected from the group consisting of at least one suture, at least one snap closure, at least one hook, a hook and loop fastener, and a second band of greater diameter or a tie, said sheet also including indicia, said sheet being sized and shaped to allow it to be introduced into operative proximity of a blood vessel laparoscopically, being composed of a material which is medically inert, sufficiently flexible to allow manipulation and resilient enough to

resist the expansion of the vessel, and wherein said sheet has a structure which will minimize tissue devascularization.

48. The device of claim 47, wherein said sheet has a width of between about 1.0 and about 3.0.

49. A method of placing a band around a blood vessel, laparoscopically, comprising the steps of: providing access to a blood vessel through a trocar, inserting a flexible band into the proximity of the blood vessel through said trocar, wrapping the blood vessel with said band; and securing said band around said blood vessel.

50. The method of claim 49, further comprising the step of isolating at least a portion of the blood vessel to be wrapped from other vessels prior to banding.

51. The method of claim 49, further comprising the steps of inserting a stent into a blood vessel, expanding said stent within vessel and securing said band around that portion of the vessel in contact with said stent.

52. The method of claim 49, further comprising the step of expanding a stent within that portion of a blood vessel wrapped by said band.

53. A device for restraining a stent in a compacted configuration for deployment comprising:

a first sheath having a first diameter, a second sheath having a second diameter which is larger then said diameter of said first sheath, at least a portion of said first sheath being disposed within said second sheath, said first sheath being movable axially within said second sheath and said first sheath being sized and shaped so as to engage and restrain a stent retained therein in a compacted position.

54. The device of claim 53, wherein said first sheath has at least one protuberance which engages a stent, said protuberance being sufficiently rigid so as to retain said stent in a compacted position.

55. The device of claim 54, wherein said first sheath has a plurality of protuberances.

56. The device of claim 55, wherein said first sheath is slidably attached to said second sheath.

FIG. 1

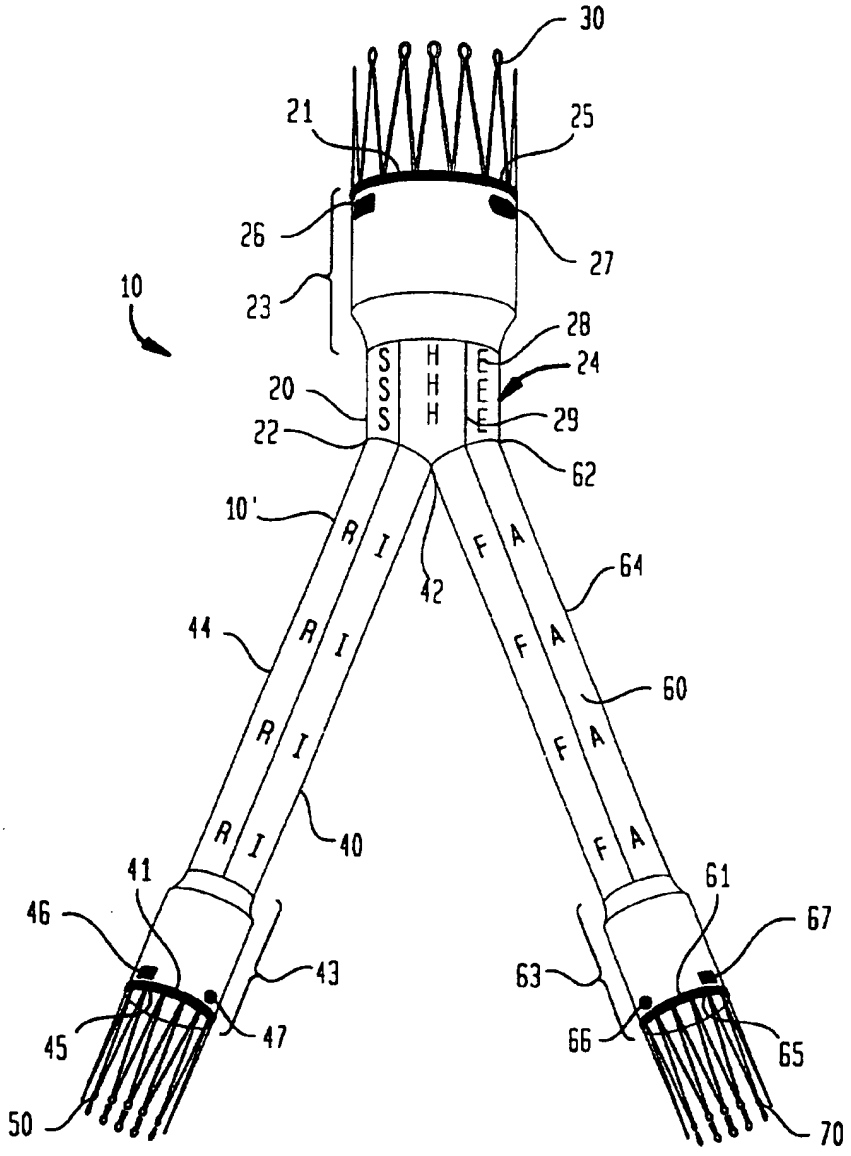
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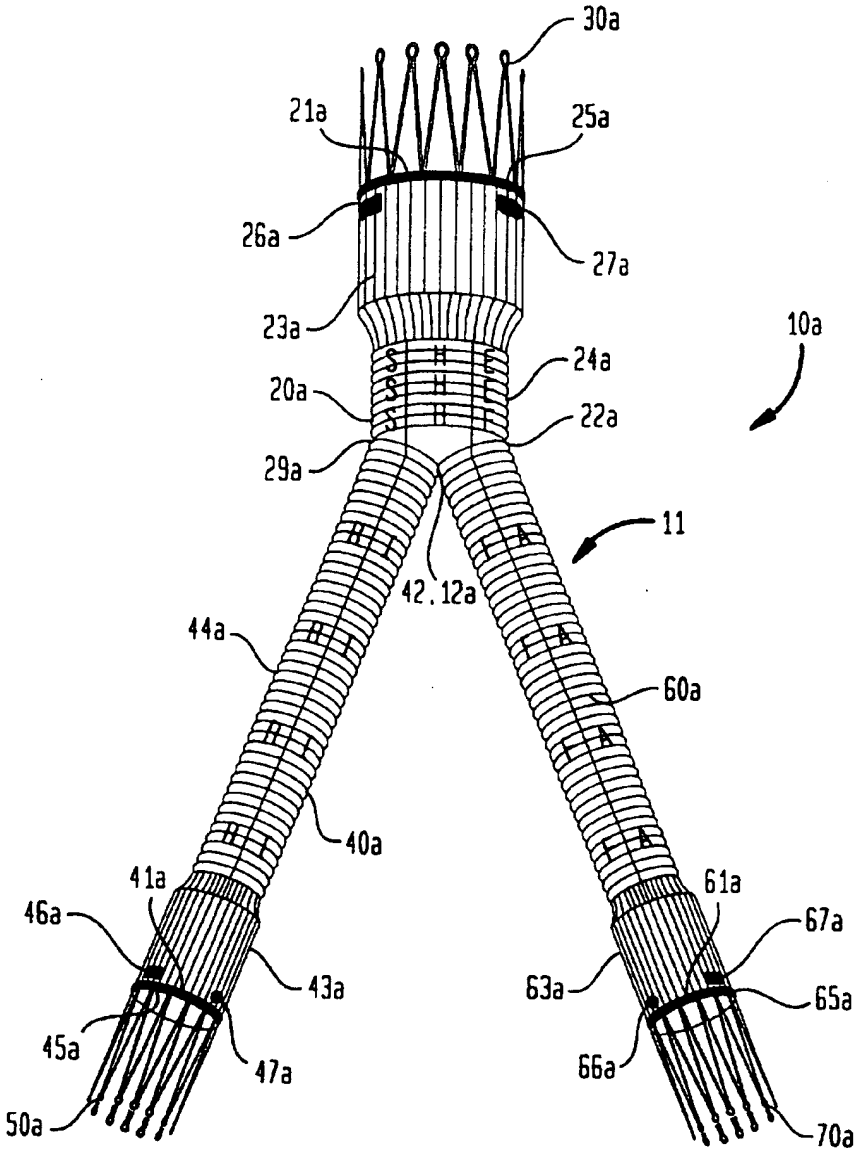
FIG. 2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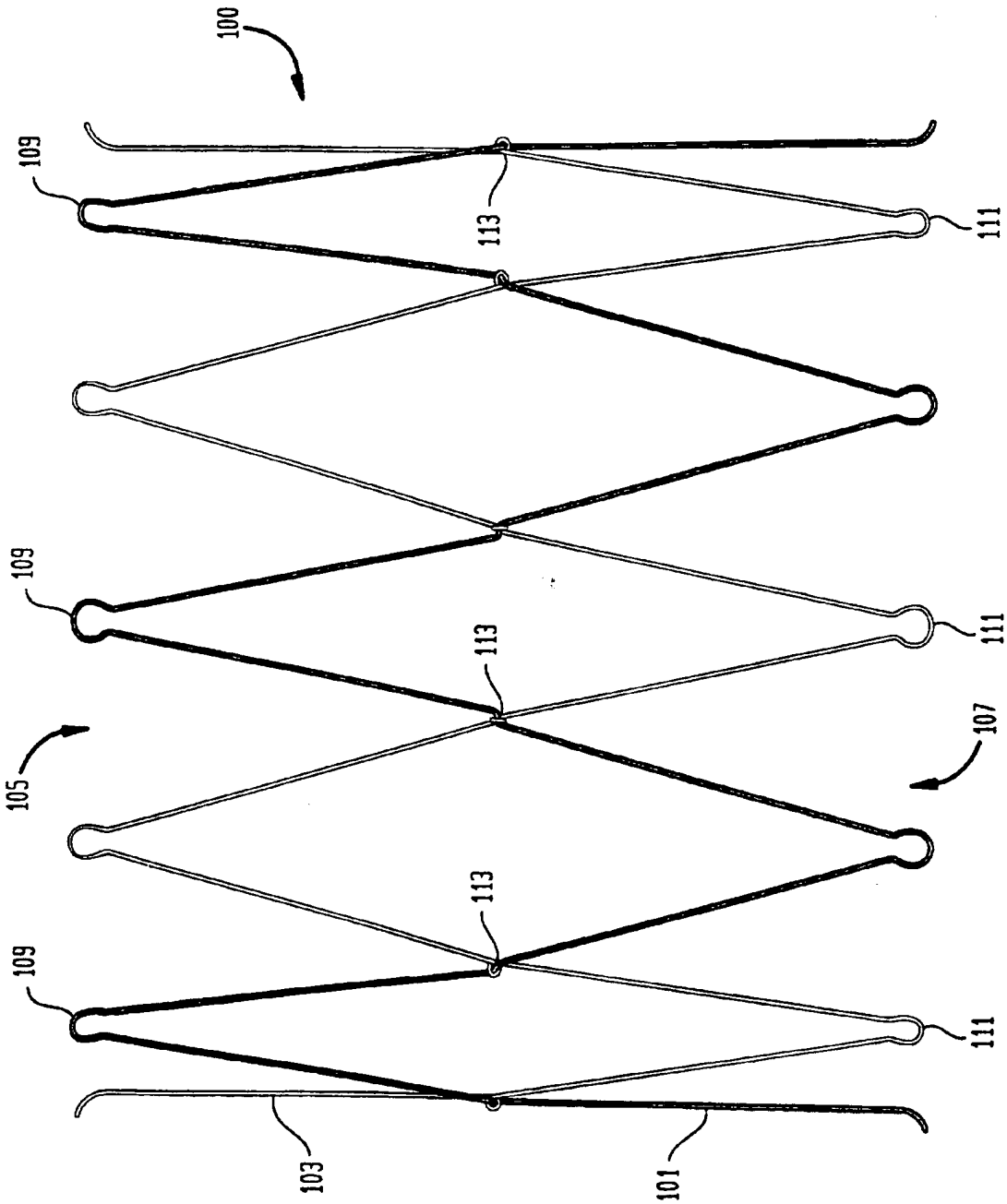


FIG. 3

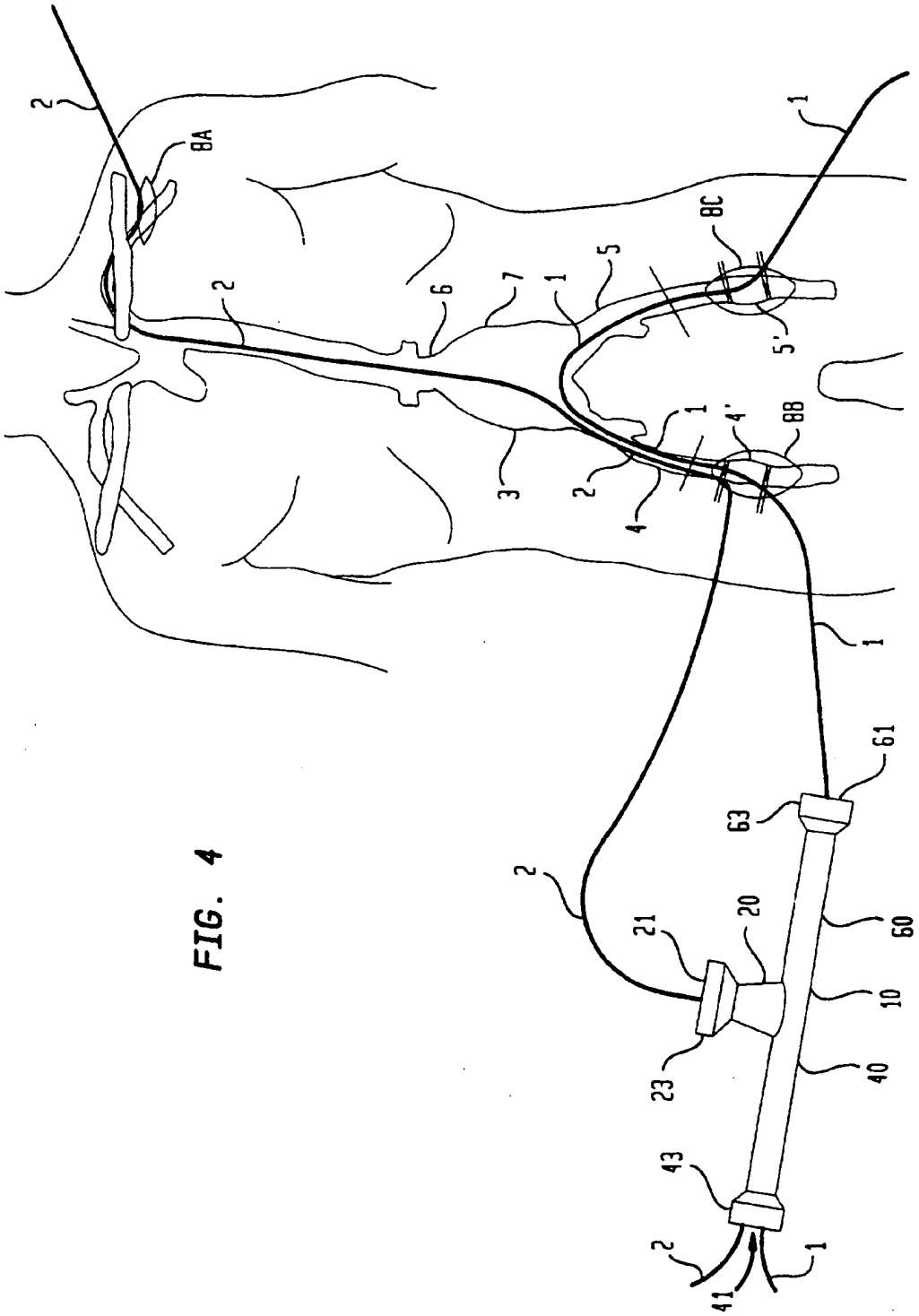
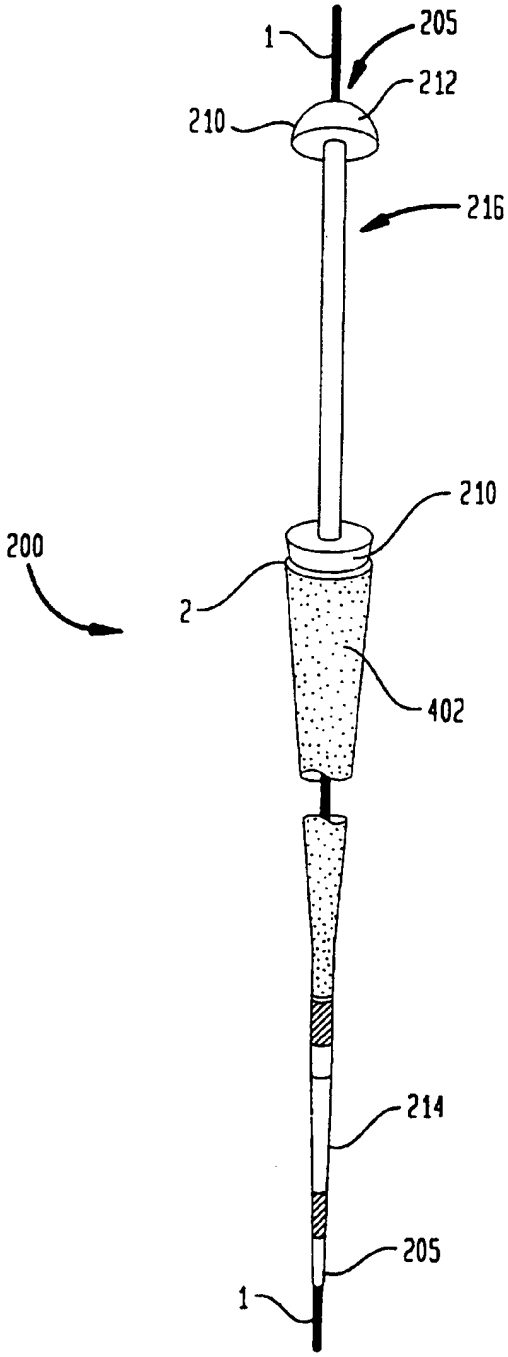


FIG. 4

FIG. 5



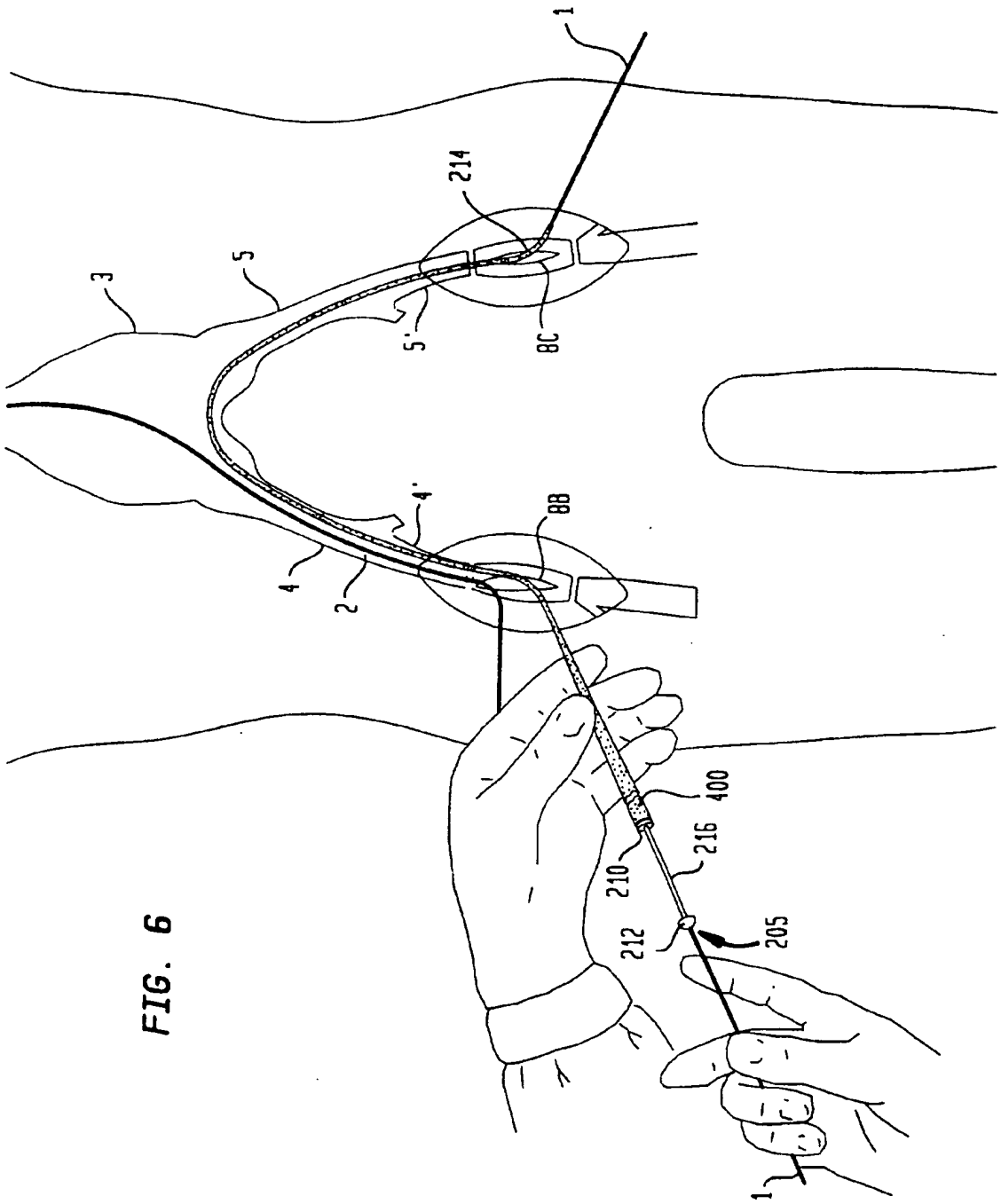
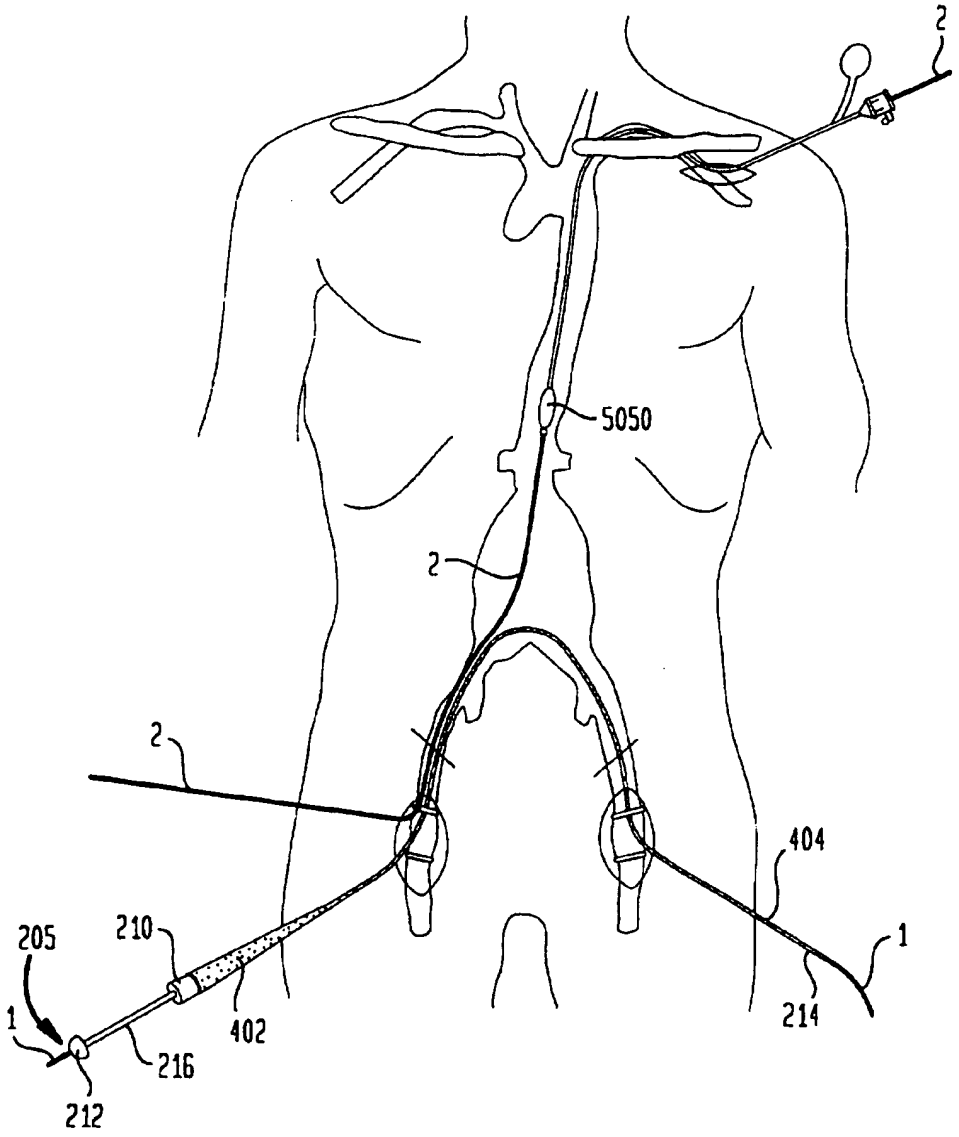


FIG. 6

FIG. 7



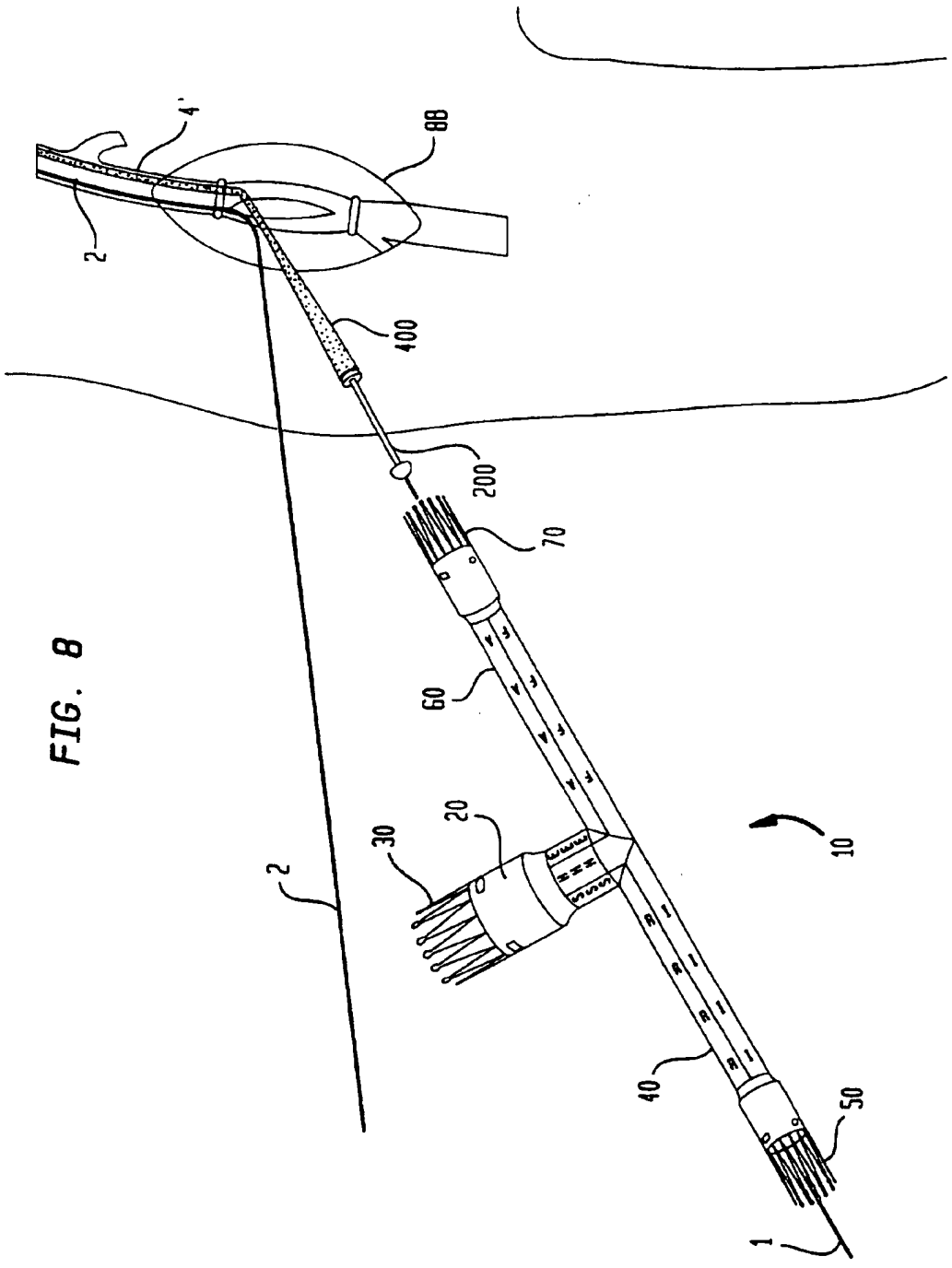
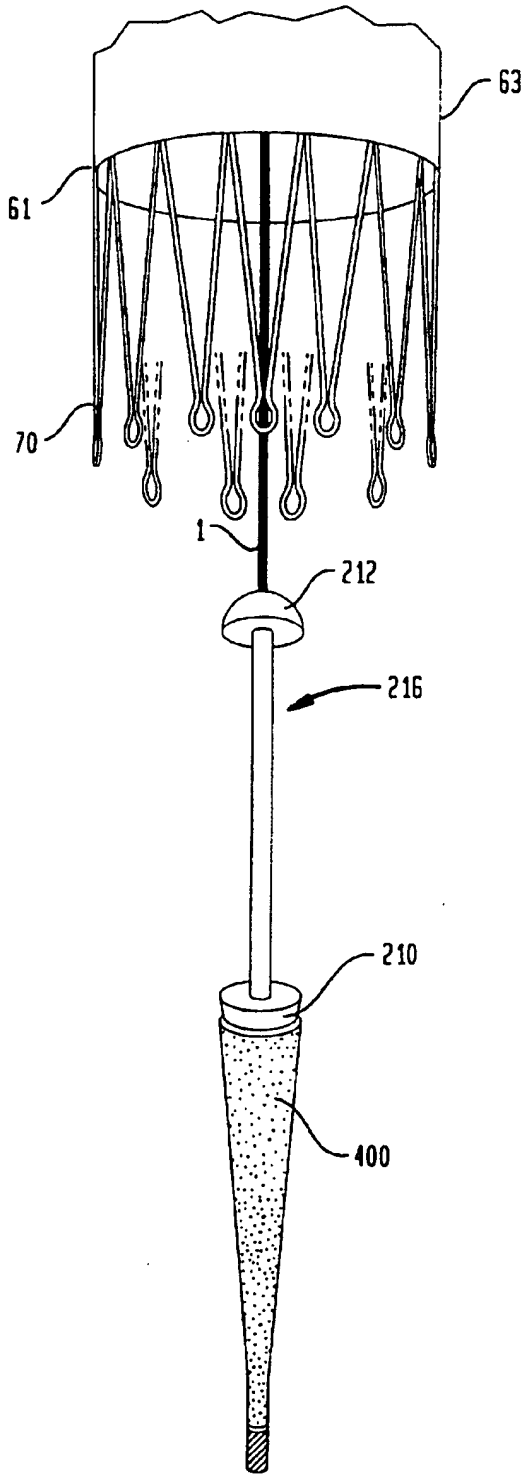
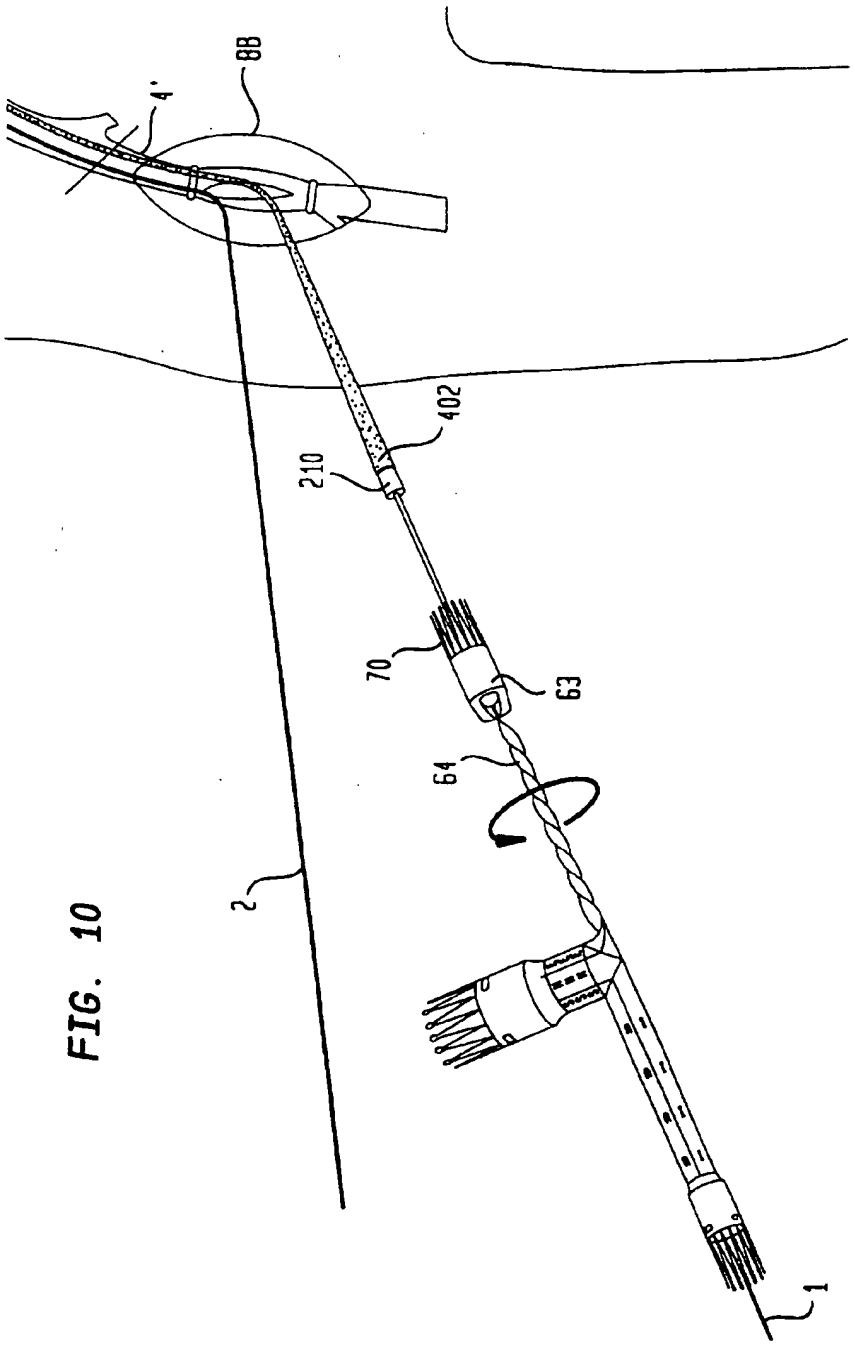


FIG. 8

FIG. 9





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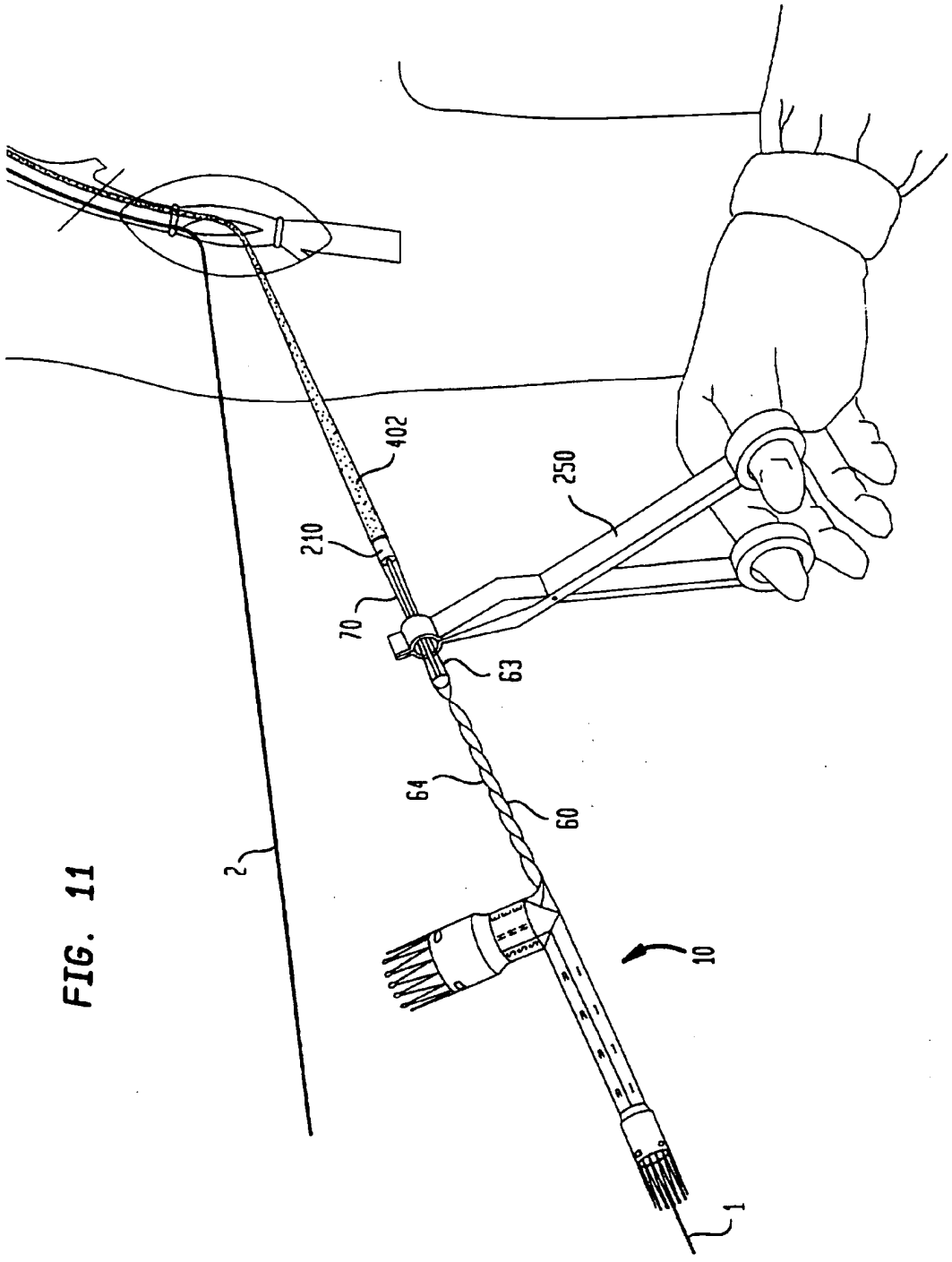
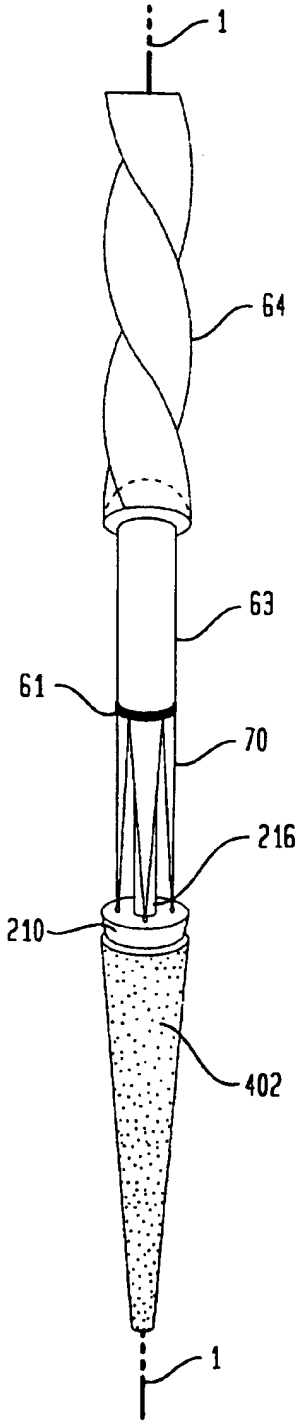


FIG. 11

FIG. 12



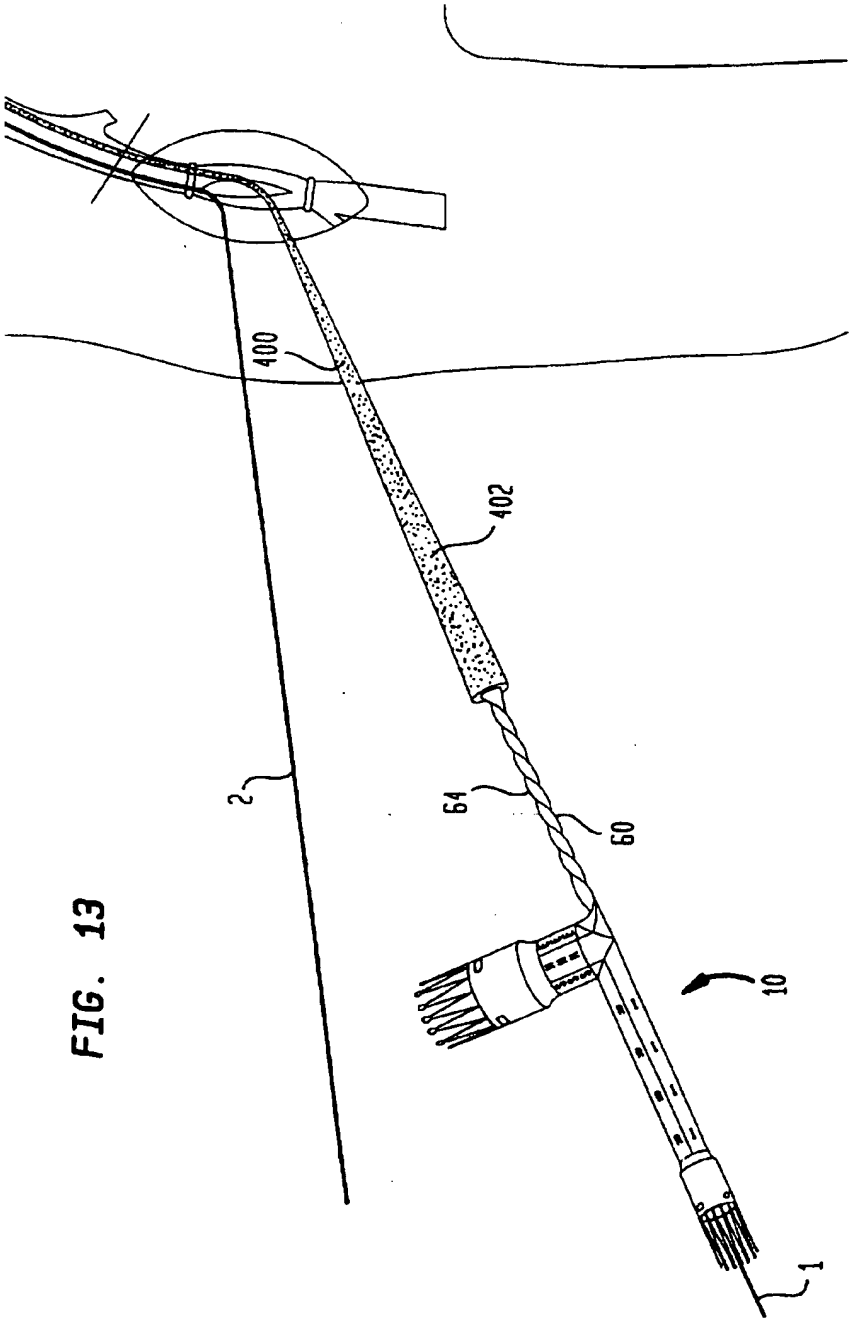
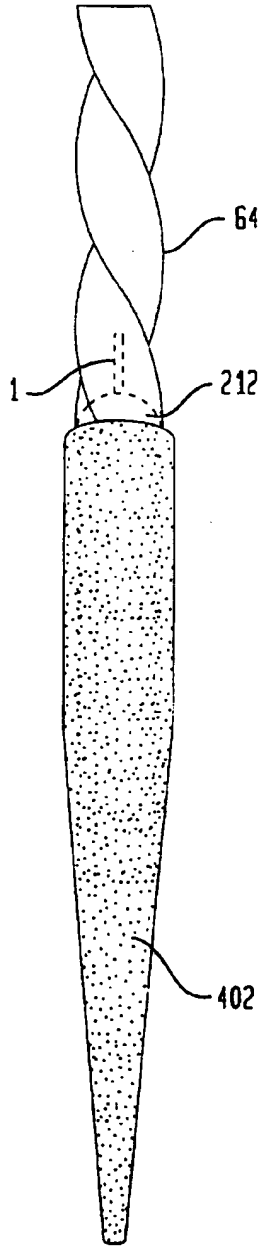


FIG. 13

FIG. 14



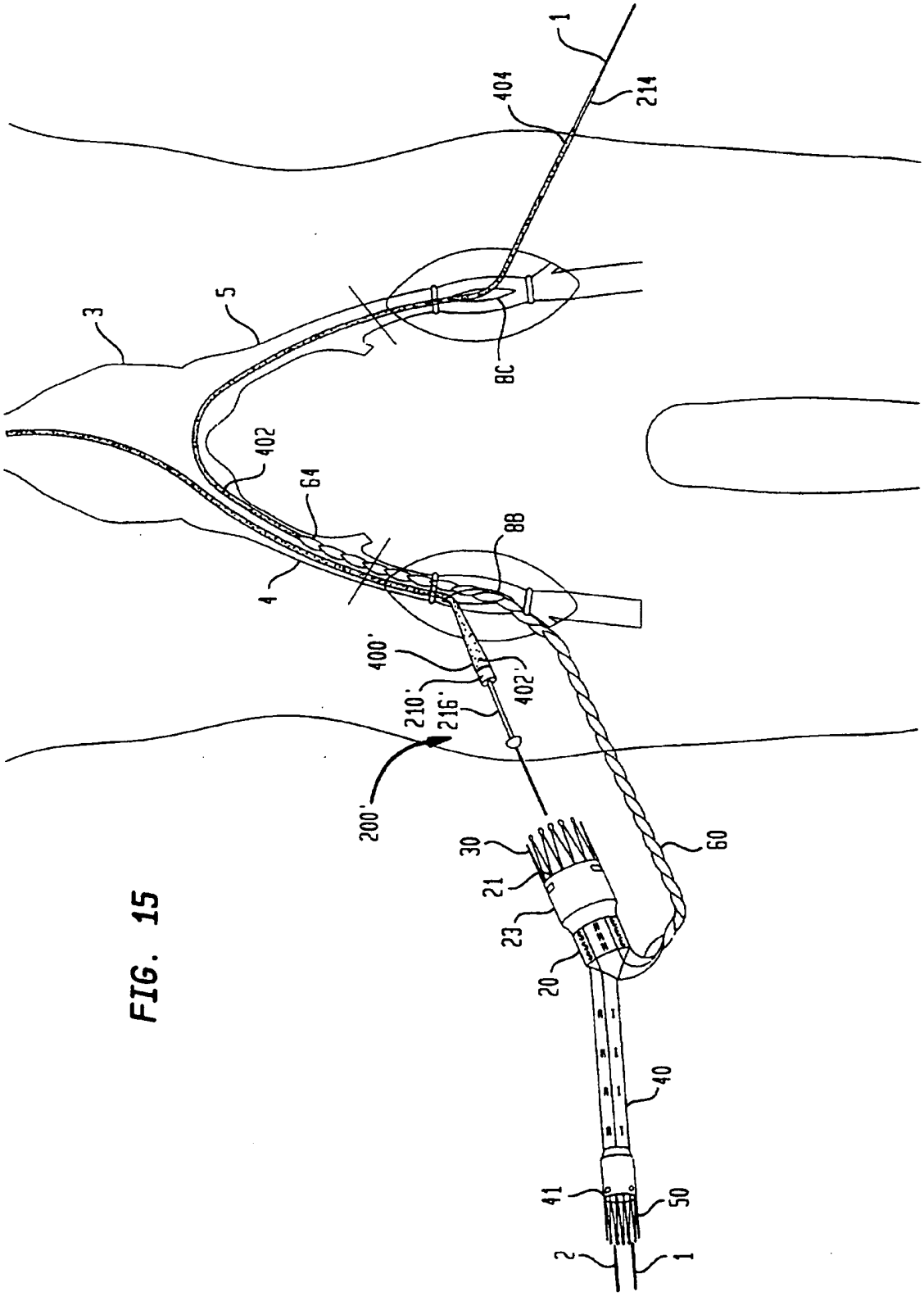

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FIG. 15

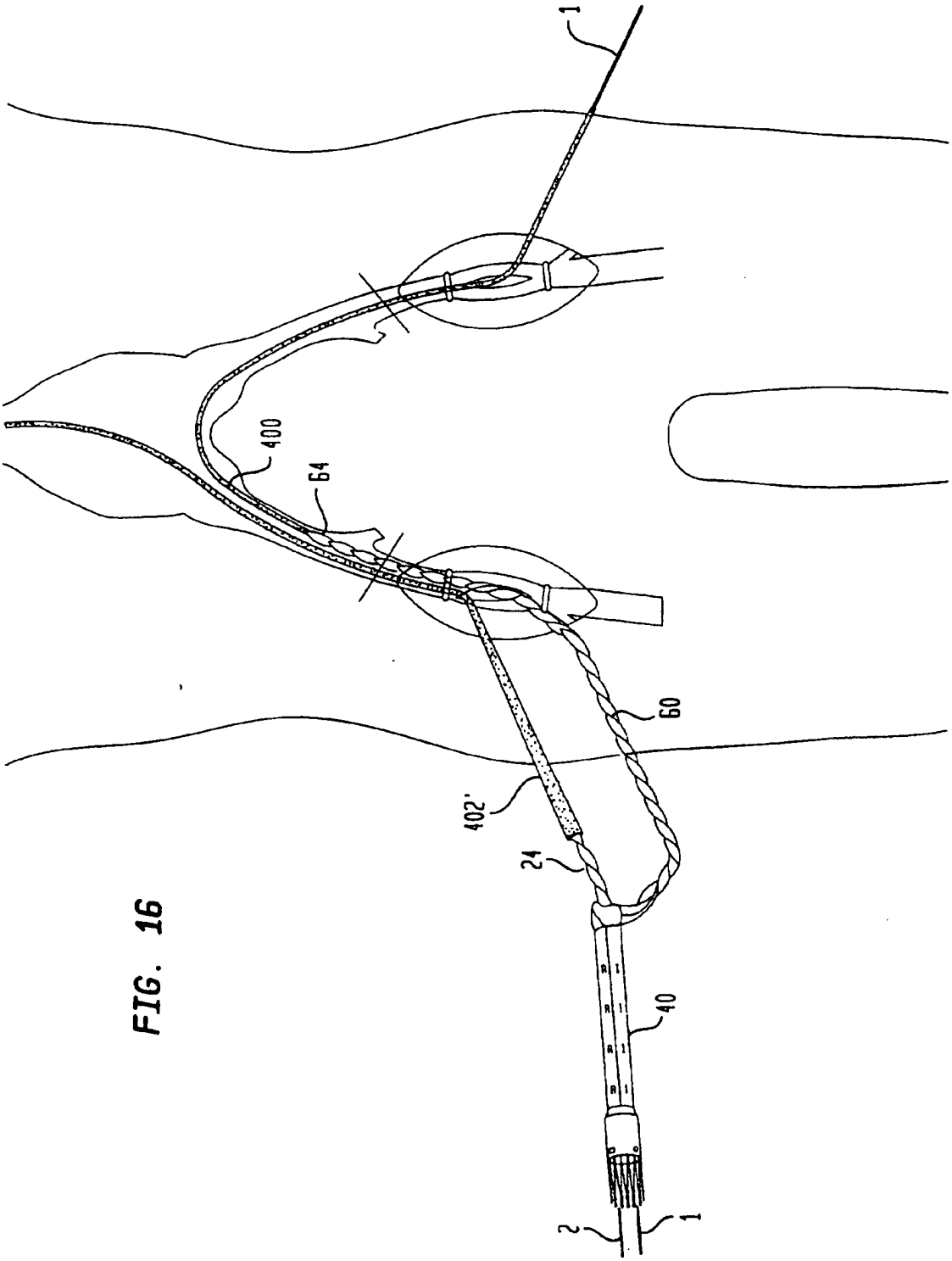

FIG. 16

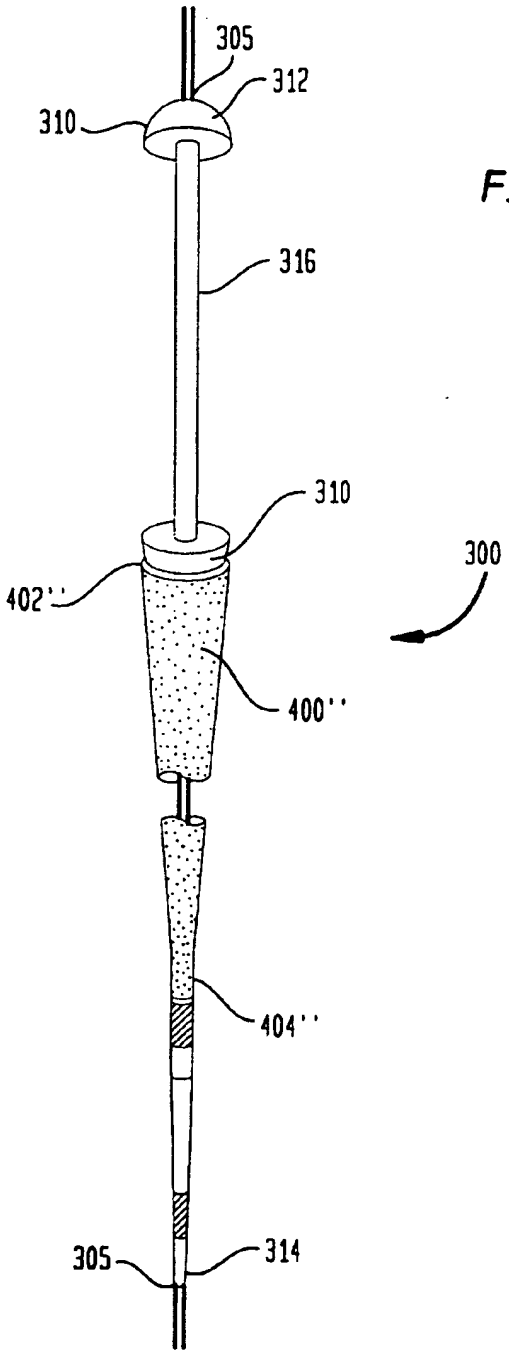
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FIG. 17

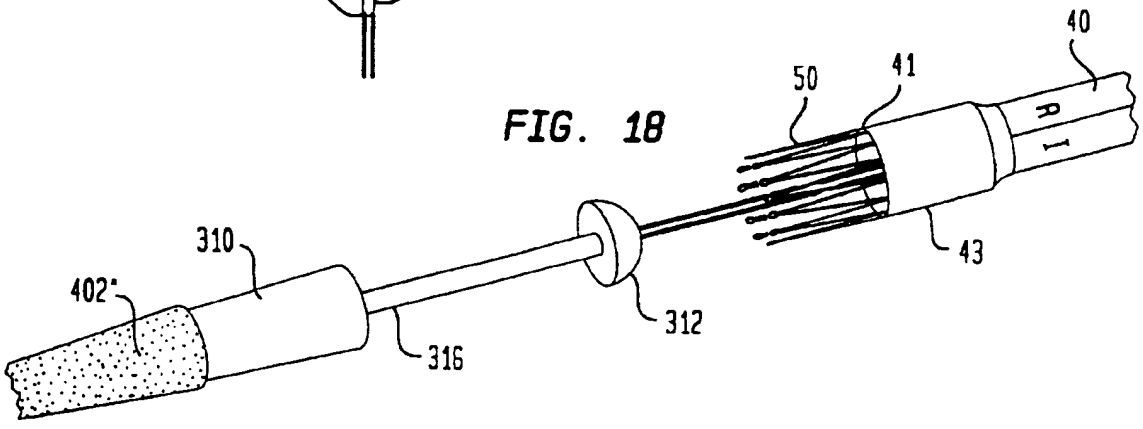
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FIG. 18

FIG. 19

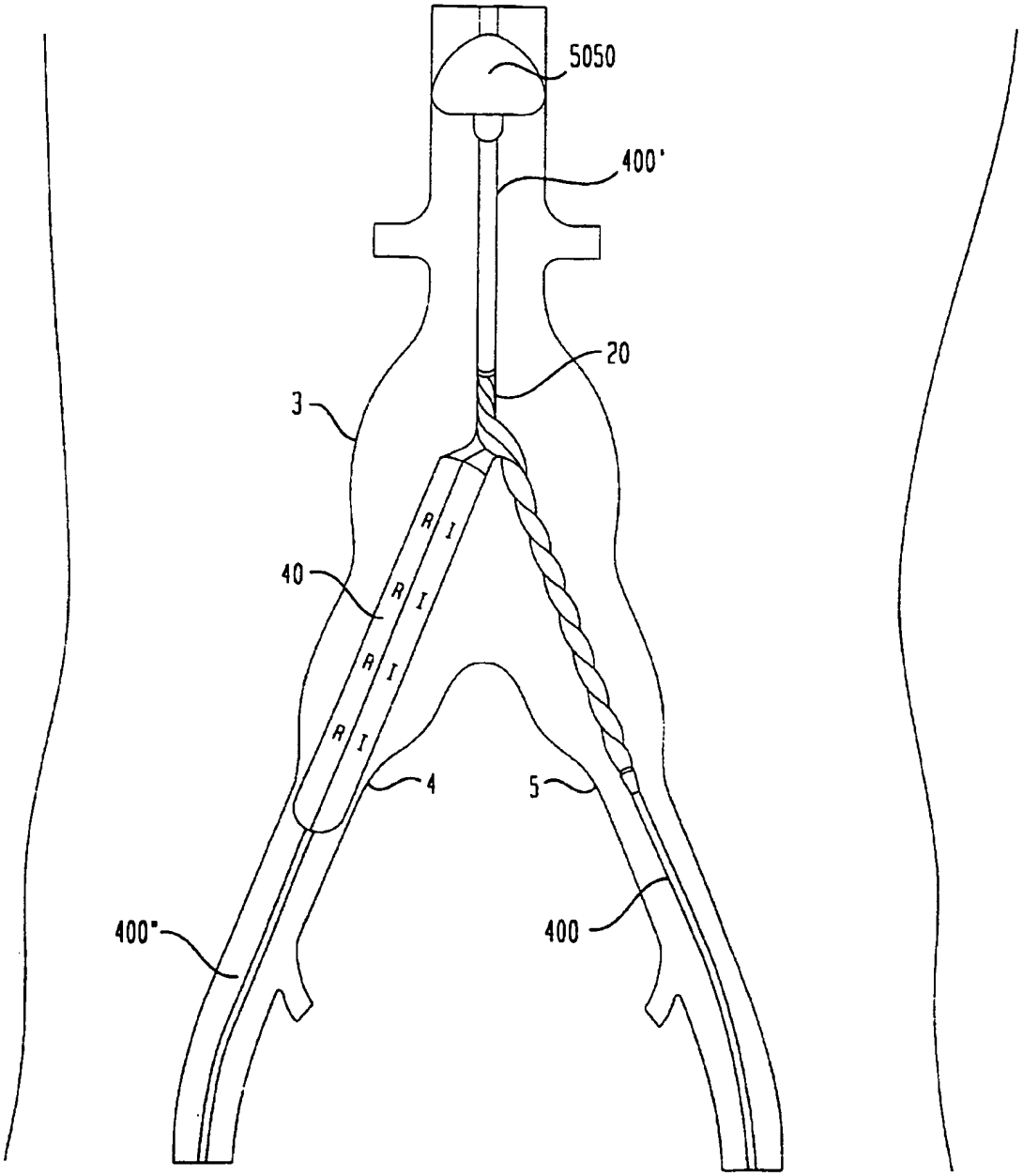

FIG. 20

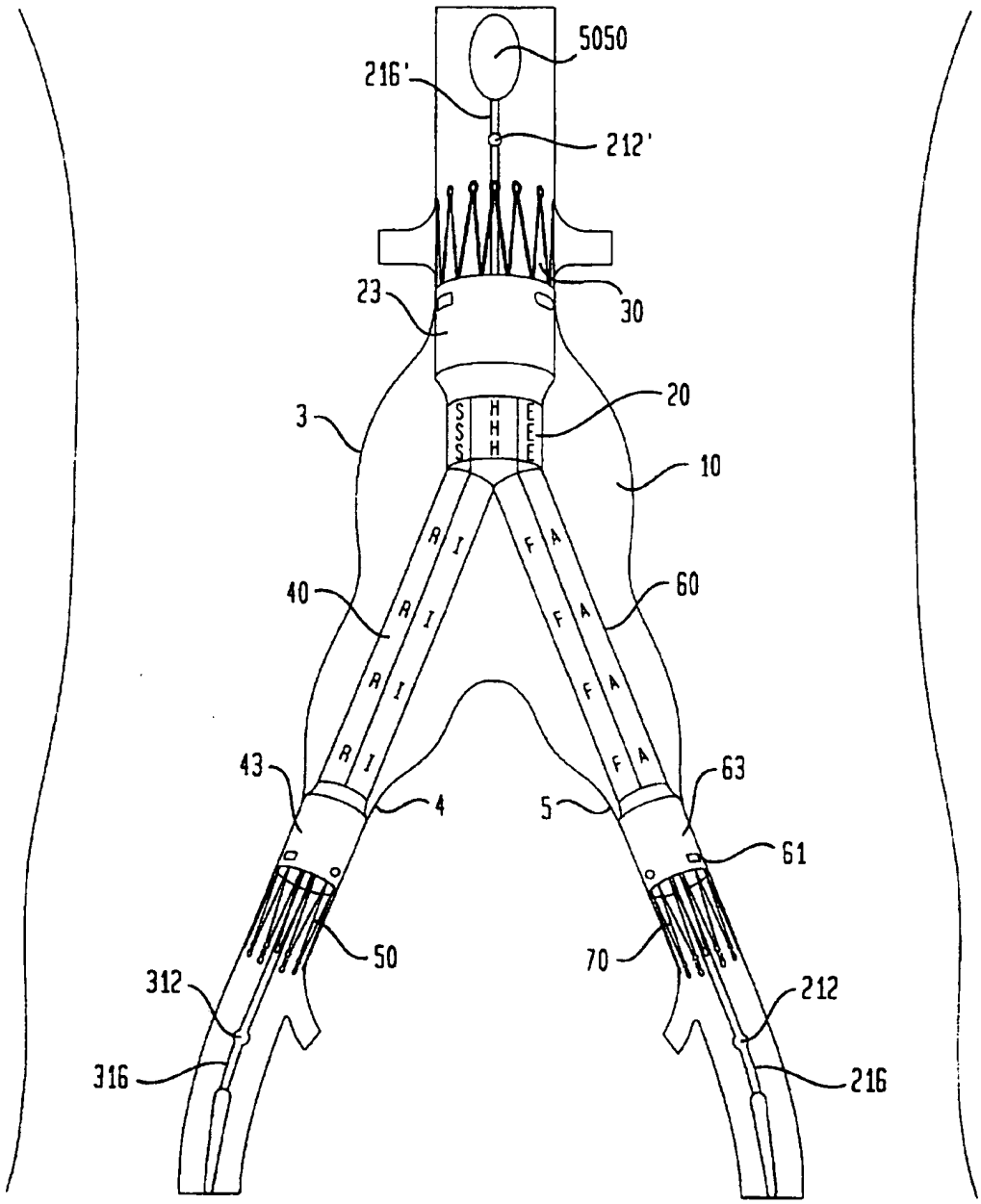
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FIG. 21

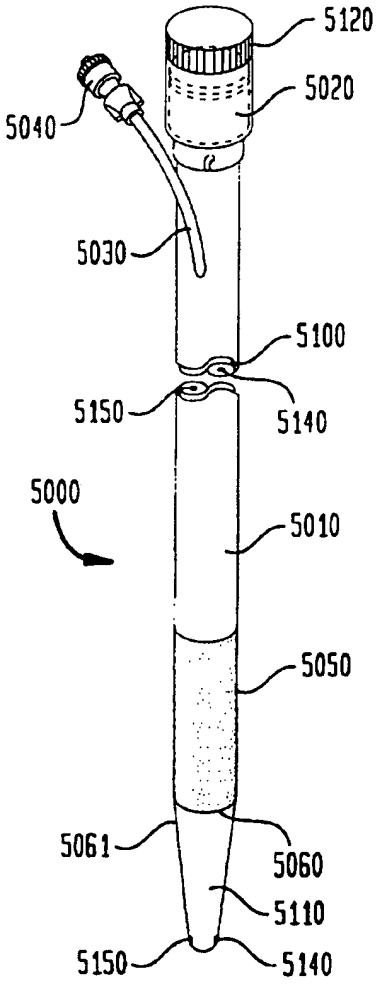


FIG. 22

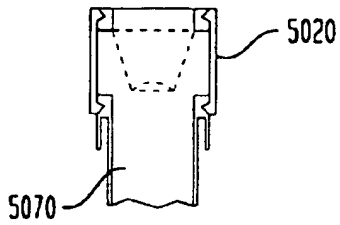
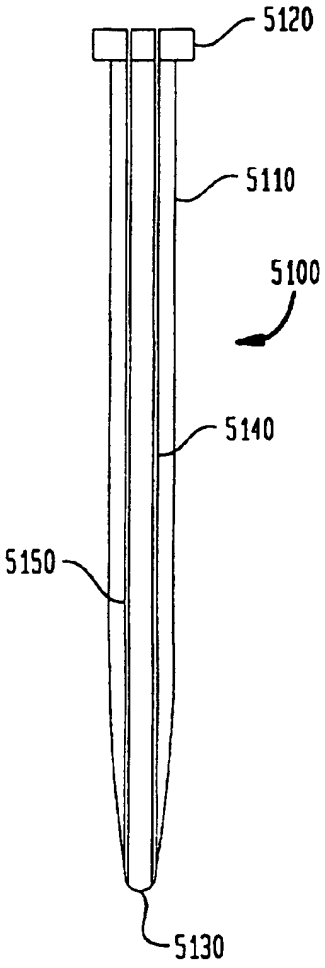


FIG. 23



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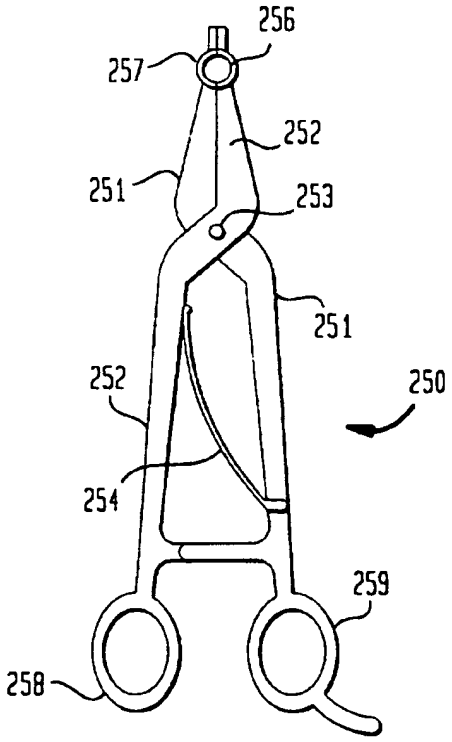
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FIG. 25

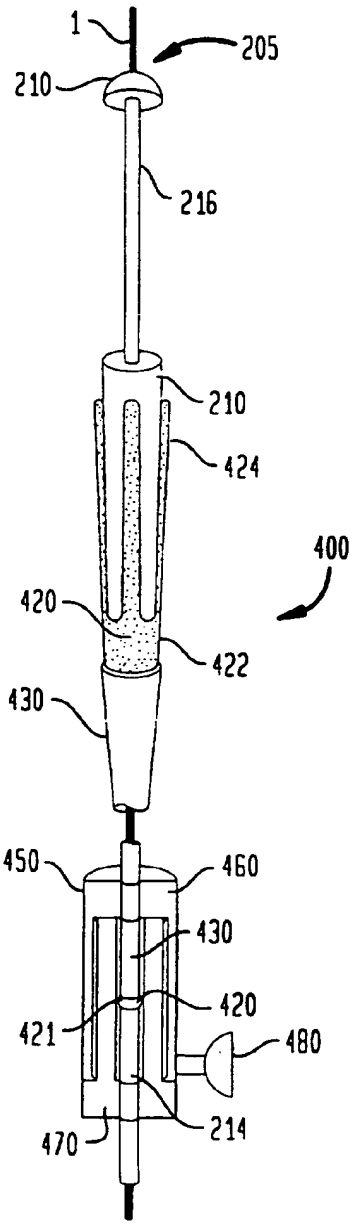
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FIG. 26

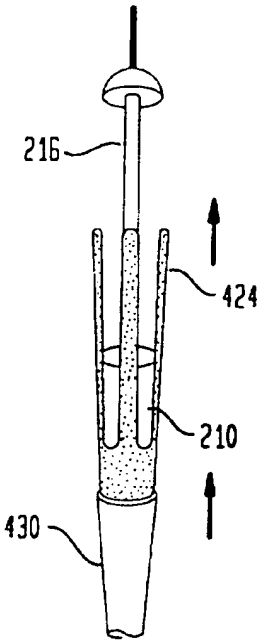

FIG. 27

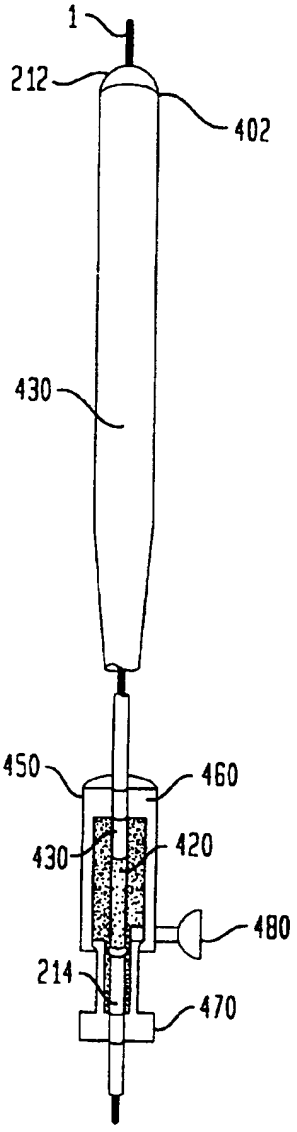

FIG. 28

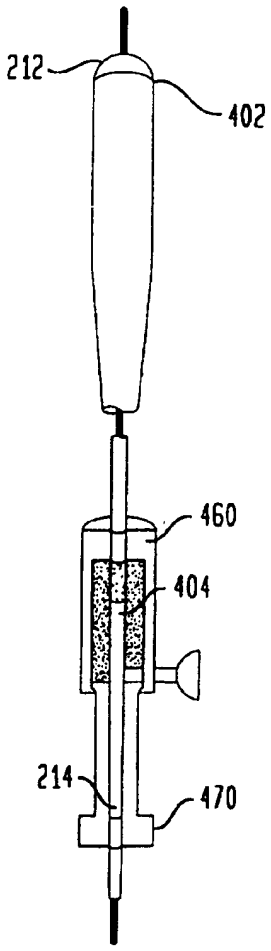

FIG. 29

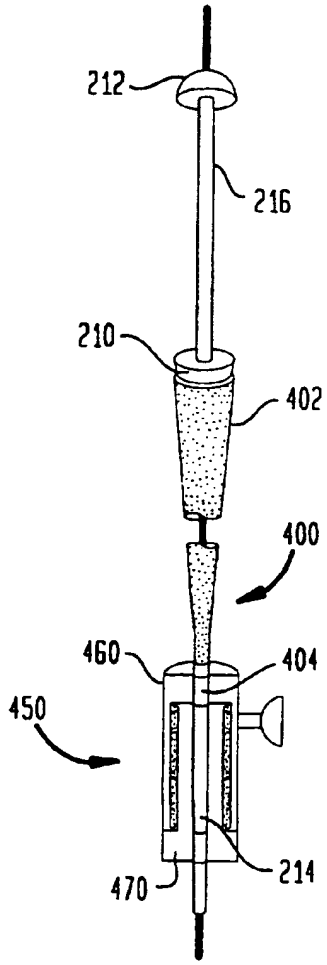

FIG. 30

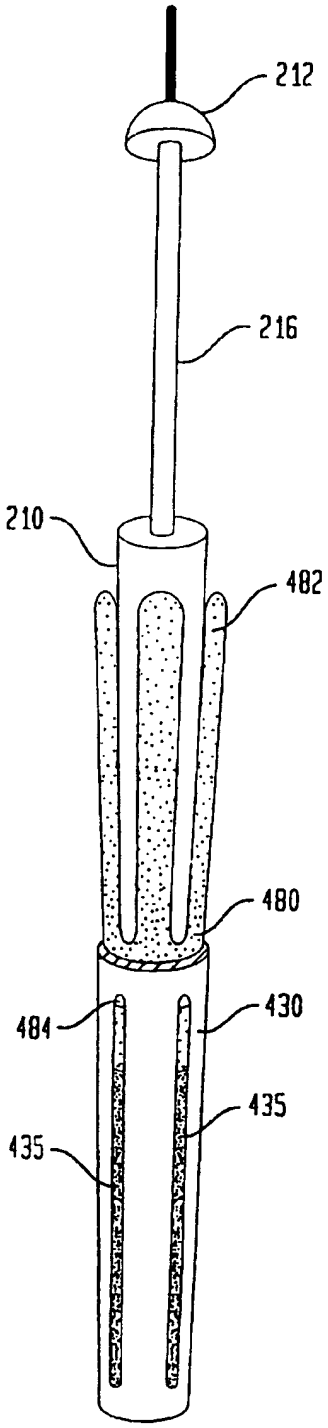
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FIG. 31

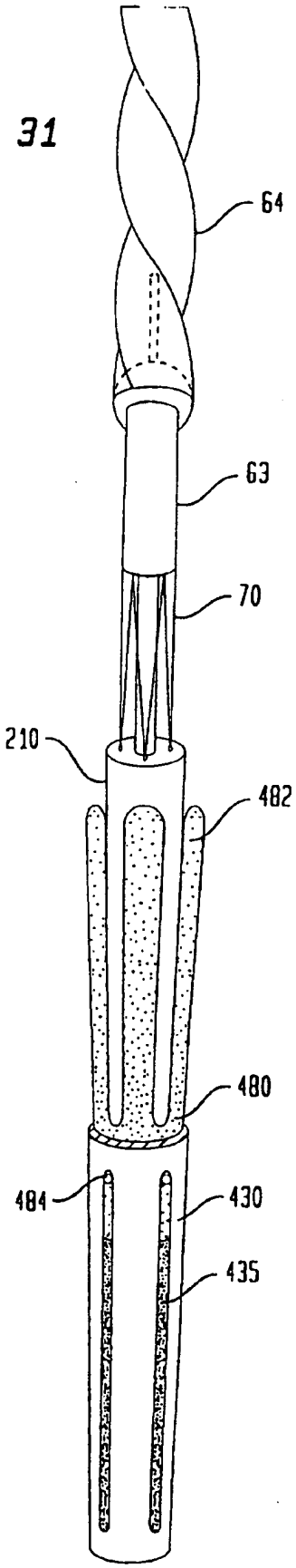
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FIG. 32

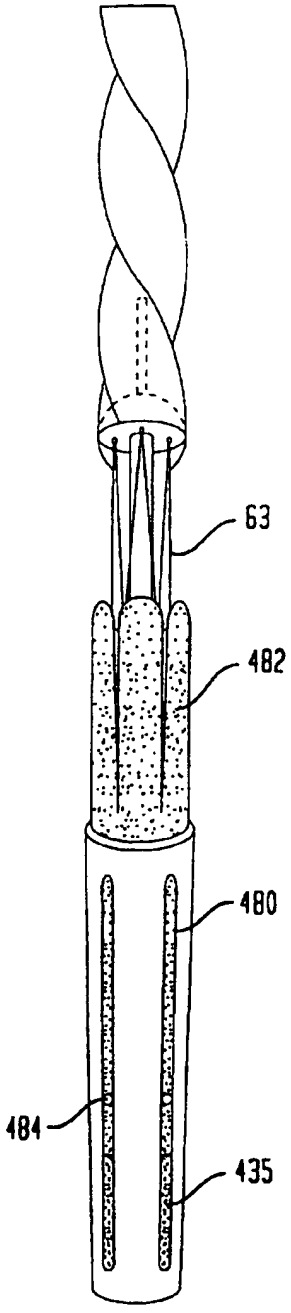


FIG. 33

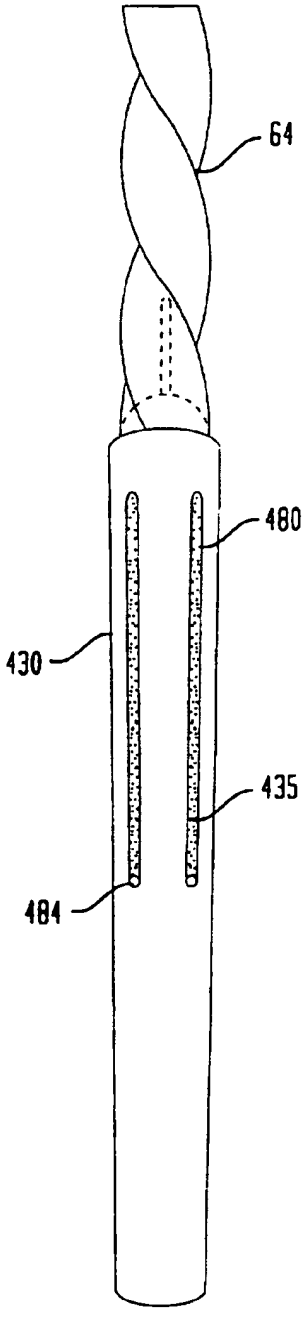


FIG. 34

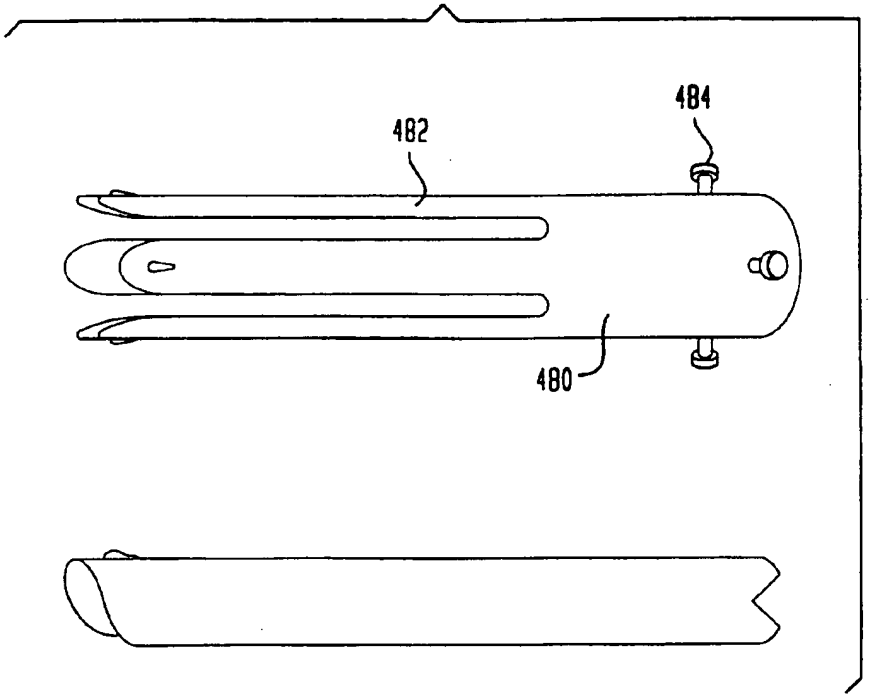


FIG. 35

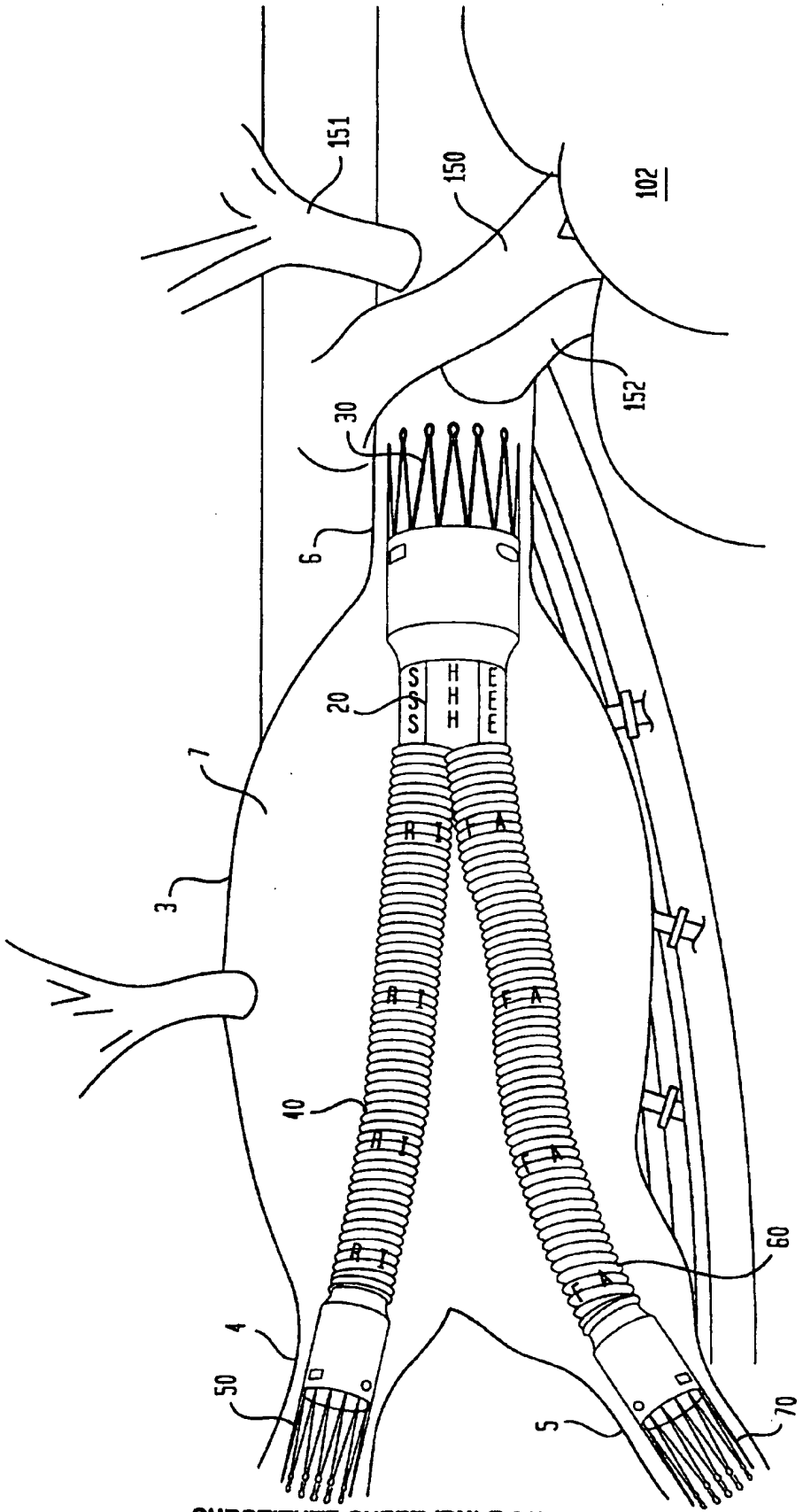


FIG. 36

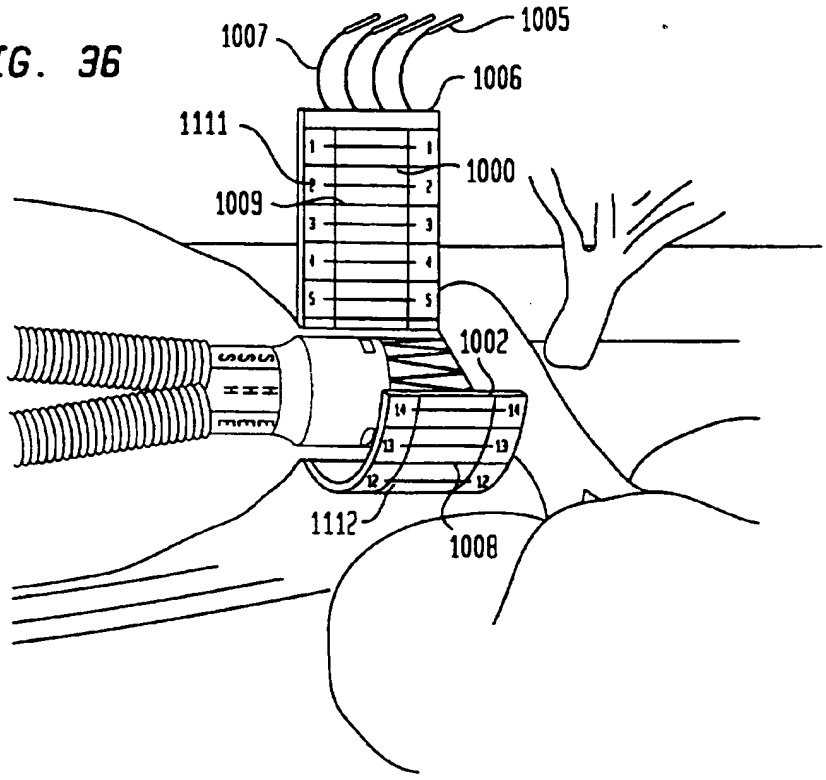

1007
1005
1006
1111
1000
1009
1002
1112
1008

FIG. 37

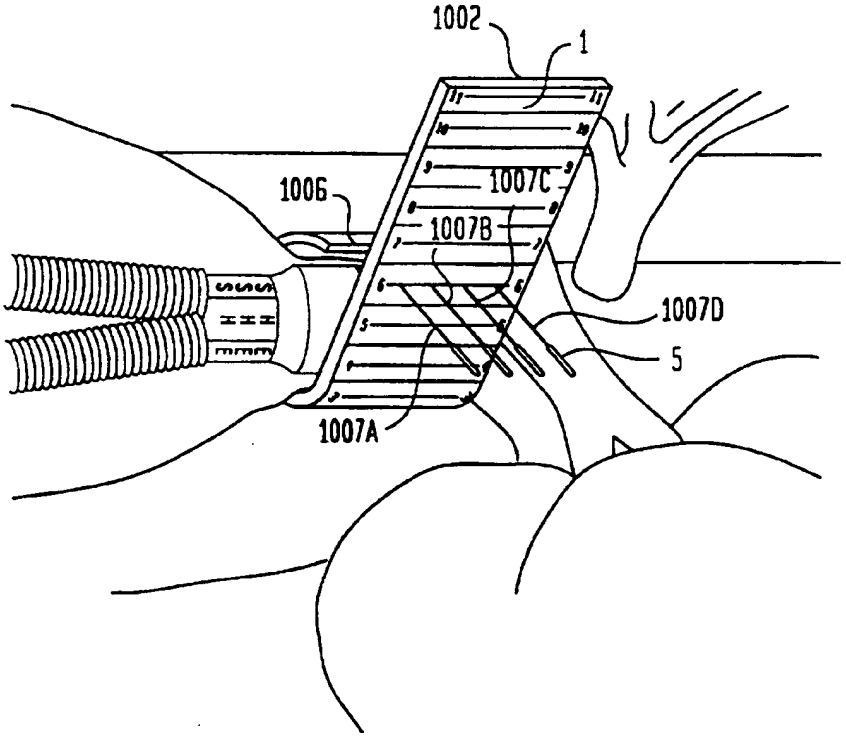

1002
1
1006
1007C
1007B
1007D
5
1007A

FIG. 38

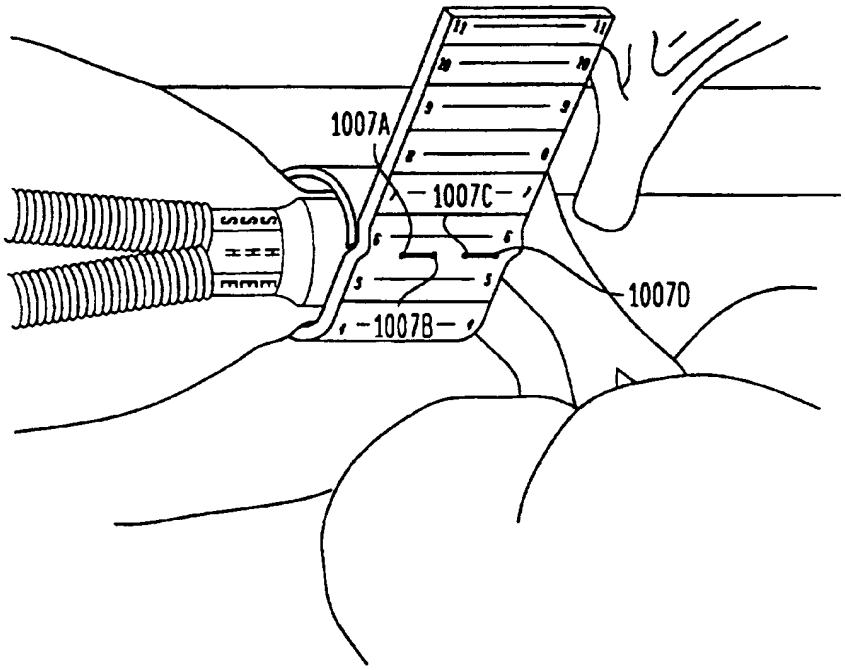


FIG. 39

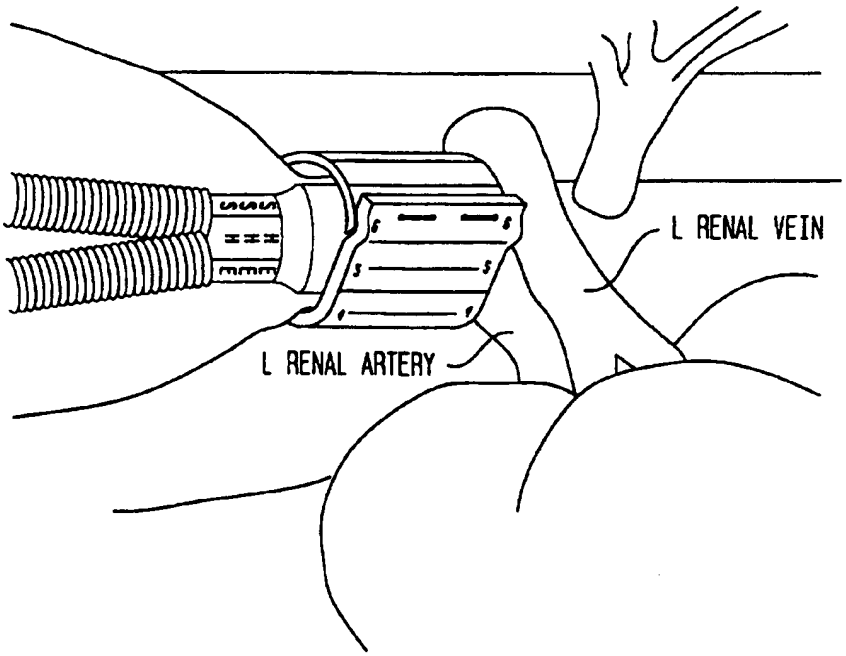
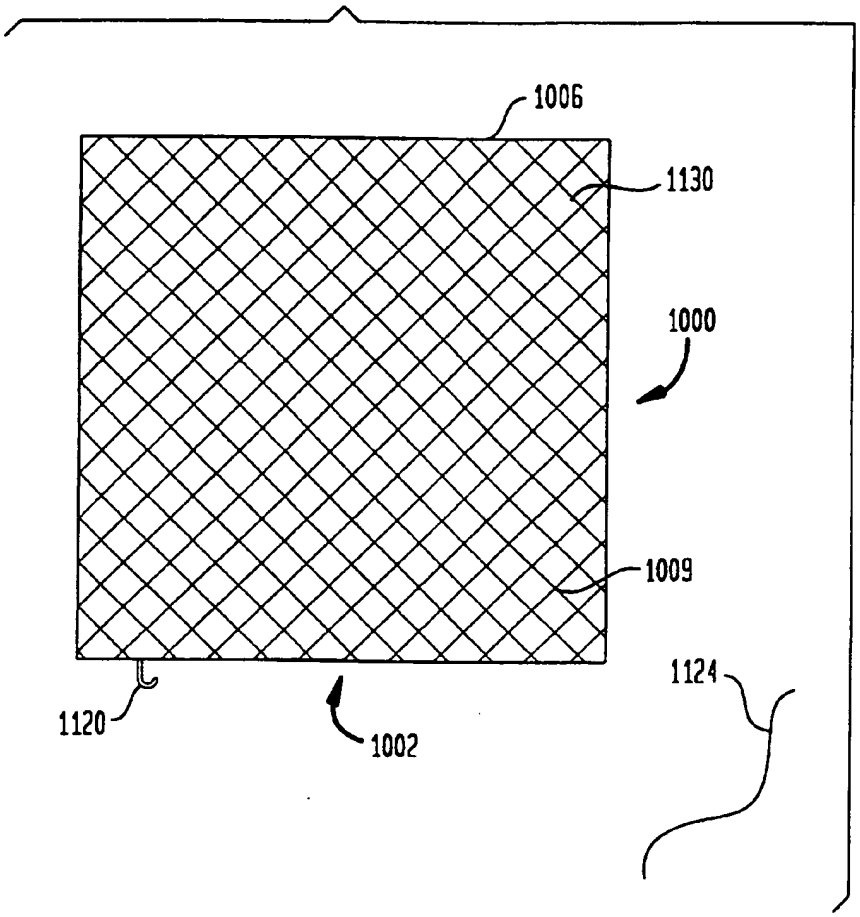


FIG. 40



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/13559

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/06; A61M 29/00
US CL :606/194, 198; 623/1, 11, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 600/36; 606/194, 195, 198; 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,489,295 A (PIPLANI ET AL.) 06 FEBRUARY 1996, COL. 2 LINES 46-60, COL. 5 LINES 22-27, COL. 10 LINE 62 TO COLUMN 11 LINE 18, AND FIGS. 1 AND 9-19.	1-56
A	US 5,211,683 A (MAGINOT) 18 MAY 1993.	1-56

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents.	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 11 DECEMBER 1997	Date of mailing of the international search report 09 JAN 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DEBRA S. BRITTINGHAM Telephone No. (703) 308-3401

Form PCT/ISA/210 (second sheet)(July 1992)*